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Abstract

Opinions and perceptions regarding the impact of new regulatory guidelines: A survey in Indian Clinical Trial Investigators

Background: Clinical research in India experienced dramatic changes with series of stringent guidelines introduced by regulatory authorities. These guidelines posed significant challenges for the clinical trial industry. **Objective:** To assess the perceptions and opinion of Indian Investigators about the new regulatory guidelines. **Methods:** We developed a survey questionnaire on recent regulatory guidelines which was hosted on a web portal. Seventy-three investigators from India participated in the survey. **Results:** Central registration of Ethics Committees (ECs) was agreed by 90.1% participants, 76.8% participants agreed to compensation of subjects for study related Serious Adverse Events (SAE's). The compulsion to include government sites in clinical trials was not agreed by 49.3% participants while 21.2% agreed to it. Restriction on a number of trials per investigator was agreed by 49.3% of participants while 40.9% disagreed. Participants (50.7%) disagreed to the introduction of audio-video (AV) recording of informed consent, 36.6% agreed and 12.7% were neutral. **Discussion:** Participants observed that post central registration; ECs have improved systems with adequate member composition, functional Standard Operating Procedures, and timely approvals. Participants agreed that compensation of study related SAE's would assure subject protection and safety. The introduction of AV consenting was strongly debated sighting sociocultural issues in the implementation of the same. **Conclusion:** Participants endorsed guidelines pertaining to the central registration of ECs, SAE related compensation. Restrictions on a number of trials per investigator and AV consenting were debated ardently. The response of the survey participants who are clinical trial investigators in India showed general acceptance, effectiveness and anticipated compliance to the new regulatory guidelines.

Key words: Clinical research, guidelines, Indian, investigators, regulatory

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INTRODUCTION

Clinical research in India experienced dramatic changes in the year 2013 with a series of stringent guidelines and laws introduced by the Ministry of Health and Family Welfare. These changes though needed and expected, posed a significant challenge for the Indian clinical research industry working towards compliance with new regulations.^[1]

Clinical trial industry in India benefitted tremendously in the past few years with the advent of economic globalization. Various multinational pharmaceutical companies found outsourcing of clinical trials to India an economically feasible alternative given the strategic advantages such as large treatment naïve base, wide spectrum of diseases, ethnic variability, English-speaking health care professionals, sound medical, and IT infrastructure.^[2,3] However, the flourishing Indian Clinical Trial Industry was eclipsed with reports of alleged malpractices and incidences of certain unethical clinical trials.^[4] Clinical research in India came under intense scrutiny with concerns being raised globally regarding the regulatory and ethical oversight of clinical trials conducted in the country. Subsequently a Public Interest Litigation was filed by a nongovernmental organization alleging unethical clinical trials carried out on children, women and mentally challenged patients in the country.^[5] Addressing these concerns the Ministry of Family Health and Family Welfare (MoHFW) took steps to strengthen the regulatory mechanism reviewing Clinical Trials in India.

An expert committee was formed under Prof. Ranjit Roy Chaudhary a noted academician and pharmacologist to review the existing policies and guidelines for approval of new drugs, clinical trials, and banning of drugs in India.^[6] Keeping in line with the recommendations given by the committee and the directives issued by the apex court, the MoHFW came up with strong confidence-building measures to restore faith in the Indian Clinical Trial Industry by issuing three back to back amendments to the drugs and cosmetic rules. Though these efforts were propelled in the right direction, they also posed significant challenges for all stakeholders in the clinical trial industry. Investigators along with Ethics Committees (ECs), Sponsors and Clinical Research Organization's was compelled to realign their structures and systems in response to the new directives. This created a complex situation for the clinical trials industry in India with global pharma companies halting or limiting trials, thus delaying the introduction of new drugs in the country.^[7] The major impact of new regulatory mandates was borne by Clinical Trial Investigators in our country. Indian investigators who had always strived towards bringing quality in patient care as well as in clinical research were deeply perturbed by the

new mandates as clinical trials conducted by them virtually came to a standstill.^[8]

Several studies and published articles have reported the research community's opinion on recently introduced regulatory mandates, but no study has reported the perception and opinion of the Indian investigator community in this context. Keeping this in perspective we undertook a survey to study the opinion and understand the perceptions of clinical trial investigators, the most important yet resilient stakeholders in India.

Objectives of the study: (a) To assess the perceptions and opinion of Indian clinical trial Investigator community about the proposed regulatory guidelines released by Drug Controller General of India (DCGI). (b) To understand the challenges encountered by them in following the changes in the regulatory scenario.

STUDY METHODOLOGY

Study population

The survey was a pilot study conducted during a 4-month period starting from February 2014 to May 2014. The survey was part of a project to develop an online portal for encouraging networking among clinical trial investigators in India. We selected email contacts of principal investigators from all four zones (East, West, North, and South) from the following database sources (Clinical Trial Registry India, Indian Society Clinical Research, Chest Research Foundation-Respiratory Research Network). We shortlisted the participant investigator list for investigators with whom we had some communication in the past. This was done to facilitate further communication with them. All the shortlisted email contacts were pooled together in an excel datasheet, and a random list was generated in excel. We contacted the first 128 investigators in the list due to time constraint and it being a pilot study. We understand this was a limitation of the study as the sample may not be a true representative of the investigators in India. Since this was a pilot study, we plan to overcome this limitation in our future studies. We also agree that cluster randomization technique would have given us a well-distributed data.

Development of study questionnaire

We developed a survey questionnaire which was hosted on a web portal (<http://www.monkeysurvey.com>) widely used to conduct online surveys. This particular survey portal was selected after reviewing its online accessibility and data security features. The idea behind using an online survey questionnaire was to reach maximum investigators in India and obtain their response in a timely manner. The questionnaire was designed keeping in perspective the

challenges posed by recent regulatory changes, as assessed from the literature review and inputs from in-house clinical trial investigators. Validation of the questionnaire was done by administering it to 10 personnel, who comprised investigators and clinical research co-coordinators working at our center. Their suggestions were incorporated, and the final questionnaire was then hosted online on the survey portal.

The study questionnaire design

The study questionnaire consisted of the following issues related to recent regulatory guidelines issued by the DCGI

- Changes in Indian ECs functions post central registration.
- Compensation to subjects for study related Serious Adverse Events (SAE's) (Rule 122DAB)
- Compulsion to include government sites in clinical trials
- Restriction on the number of trials handled by the Principal Investigator
- Introduction of audio-video (AV) recording of informed consent (IC) in India
- Need to form a national network of clinical trial investigators.

Participants were asked to denote their opinion on the above issues on a five-point scale (Strongly Agree, Agree, Neutral, Disagree, and Strongly disagree). In addition, participants were also requested to provide justifications to their opinion in 150 words.

Survey recruitment methodology

The Institutional EC was informed about the proposed survey and an exemption from the review was obtained as it was an observational survey and involved no more than minimal risk to research participants. An invitation email was sent to all investigators in the 1st month which contained information about the purpose of the survey and web link to the online survey portal. The invitation email mentioned that participants who wished to be a part of the survey could proceed by accessing the online survey web link provided. It was also stated that the survey report would be compiled and sent to the regulatory authorities and also published in a peer-reviewed journal. An acknowledgment receipt was requested on the delivery of the email. A reminder email was sent to all investigators, who acknowledged receipt of the mail, but did not respond requesting them to participate in the survey in the 2nd month. After assessing the response, we made 2 follow-up calls in the last 2 months requesting the nonresponsive investigators for survey participation. The investigator responses were stored in a central database, which was accessed only by the study team. Individual responses were compiled in a format where names and other identification marks were removed prior to analysis.

Statistical analysis

Investigators were asked to denote their opinion on the above issues which were indicated on a five-point scale (Strongly Agree, Agree, Neutral, Disagree, and Strongly disagree). The responses provided by investigators were analyzed quantitatively. The qualitative data obtained in the form of justifications were analyzed quantitatively. The justifications provided were grouped based on the degree of agreement. A category system was constructed based on major themes identified in the data. Each justification in the grouped data was coded as per the category. The frequency of data in each category was analyzed quantitatively.

The descriptive data were analyzed using thematic analysis technique to gain a substantial insight into the justifications provided by investigators to their responses. Patterns were identified through a rigorous process of data familiarization, data coding, data categorization, and pattern formation. The categorization is based on the preselected themes which were relevant to the study objectives. The analyzed dataset is presented in tabular format.

RESULTS

We sent the survey to 128 Investigators in India through email which consisted of a web link to the study questionnaire hosted on the survey website. A total of 73 investigators responded to the survey. We did not receive a response from 55 investigators. This was attributed to nonfunctional email addresses (15), nonwillingness to participate in the survey (14), and investigator's busy schedule (26) as conveyed to us during the telephonic follow-up. The survey received a response rate of 57%. The demographics of survey participants are represented in Table 1.

Table 1: Investigator demographics

Description	Number
Investigators approached for survey	n=128
Investigators responded	n=73
Mean age (years) (n=36)	49.6±8.55 (n=36)
Geographical area (n=71)	North zone=9 West zone=34 East zone=5 South zone=22 International=1
Medical specialty (n=62)	Oncology (n=18) Cardiology (n=4) Respiratory (n=22) Diabetes (n=8) Others (n=10)
Clinical research experience (year) (n=31)	16.25±7.65 (n=34)
Private/government affiliations (n=71)	Private=54 Government=17

Investigators opinion to recent regulatory changes

We assessed the investigators opinion on recently introduced regulatory changes which was analyzed and represented quantitatively [Table 2].

Central registration of ECs was strongly agreed by 53.5% and agreed by 36.6% participants. The regulatory mandate of compensating subjects for SAE's (Rule 122 DAB) was strongly agreed by 34.8% and agreed by 42% of participants while 11.6% disagreed to it.

With reference to the issue of compulsion to include government sites in clinical trials, 23.9% investigators disagreed, 25.4% strongly disagreed, and 29.6% investigators chose to remain neutral while 11.3% agreed to it. Almost 95% of participants disagreeing to this mandate were from private institutions.

When queried on whether there should be a restriction on the number of trials being done by an investigator, 16.9% strongly agreed, 32.4% agreed while 15.5% disagreed 25.4% strongly disagreed to it.

Also, 29.6% participants disagreed on the new mandate which made it essential to introduce AV recording of IC process in India while 15.5% strongly agreed to it, and 12.7% remained neutral.

The descriptive data provided in the form of justification for the degree of agreement with the changes in mandate were analyzed and presented under each theme.

- Central registration of ECs: 39 participants provided justifications to their opinion on this issue. The justifications received were as follows: Strongly agreed (24), agreed (12) neutral (1), disagreed (1), and strongly disagreed (1). Participants strongly agreeing to this mandate put forth that central registration has increased efficiency, responsibility, and accountability of ECs (41.7%), imparted legal status to the EC (20.8%), and standardized EC procedures (37.5%). Participants, who were neutral or disagreed, put forth administrative hurdles such as lengthy paperwork and large geographical distance with the DCGI office as their reasons for disagreement.

- Study related SAE compensation: We received 38 justifications on this issue as follows: Strongly agreed (12), agreed (16), neutral (4), disagreed (5), and strongly disagreed (1). Participants strongly agreeing to this mandate felt it was essentially patient's right to receive compensation (67%), moral responsibility of investigators to provide compensation (17%), and provision essential for study related SAE (16%). Participants disagreeing primarily sighted causality assessment important for decision on compensation (20%), unclear guideline (40%), guideline not encouraging research (20%), and guideline may have potential to bias (20%).
- Compulsion to include government sites in clinical research: We received 7 reasons from participants in agreement to this mandate while 12 reasons were provided by participants who disagreed to it. Those in agreement with the mandate expressed that including government hospitals will help these hospitals in capacity building, trials will be regularized, and poor patients accessing government hospital will be benefited. We found that participants who disagreed with mandate were concerned about the various challenges encountered in government hospitals which would be a hindrance to clinical trial operations such as poor infrastructure, lack of patient care and management, poor record keeping, and lack of quality control measures. Participants also highlighted that lack of well-trained staff and bureaucratic policies would affect conduct clinical trials in government hospitals. Participants suggested in the same context that clinical trial sites should be selected on basis of experience, qualifications, dedication, and performance of trial staff and good infrastructure [Table 3].
- Restriction on a number of trials being done by participants: The reasons provided by participants on the above rule are summarized in Table 4. Participants who agreed have put forth that the above mandate will increase investigator responsibility, accountability and oversight on clinical trials along with improvement in quality of data generated. The reasons put forth in disagreement category were an emphasis on time management, well trained, organized, and skilled site staff along with experienced investigator who can

Table 2: Investigators opinion on recent regulatory changes introduced by DCGI (n=73)

New regulatory guidelines	Strongly agree (%)	Agree (%)	Neutral (%)	Disagree (%)	Strongly disagree (%)
Central registration of EC	53.5	36.6	4.2	4.2	1.4
Compensation for study related SAE	34.8	42.0	11.6	8.7	2.9
Compulsion to include government hospitals for clinical trials	9.9	11.3	29.6	23.9	25.4
Restriction on trial numbers per investigator	16.9	32.4	9.9	15.5	25.4
Introduction of audio-video recording of informed consent	15.5	21.1	12.7	29.6	21.1

EC=Ethics committee, SAE=Serious adverse event, DCGI=Drug Controller General of India

efficiently handle multiple trials. Participants who disagreed also expressed that the above mandate cannot be applied to orphan drugs with 2–3 subjects per trial.

- AV recording of IC process: We received 13 responses in agreement category (strongly agreed, agreed) and 25 responses in disagreement category (strongly disagreed, disagreed) which have been represented in [Figure 1]. Participants in agreement with the above mandate felt that it will increase investigator responsibility and accountability toward the IC process (38.5%) along with offering legal protection to participants (53.9%). Those in disagreement felt that it would cause subject confidentiality issues (20%), anxiety-discomfort (28%)

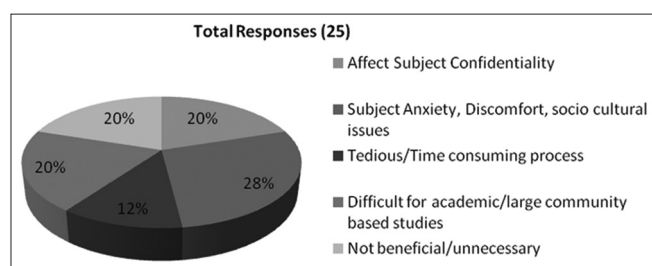


Figure 1: Justifications of investigators on disagreement for audio-video consent process

Table 3: Analysis of justifications for disagreement on compulsion to include government hospitals as sites for clinical trials

Categories	Responses (12)
Poor infrastructure/facilities	Limited or lack of facilities, ill-equipped, lack of state of the art facilities, lack of advanced medicines, lack of research facilities (5)
Performance/patient care	Suboptimal work and patient care, abysmal record keeping, no quality control and poor performance (5)
Personnel/staff	Lack of expertise and awareness, lack of commitment and interest, lack of responsibility, time and dedication (1)
Administrative Suggestions	Legal and bureaucratic problems (1) Selection criteria for clinical trial sites: Performance, dedication, staff experience and hospital infrastructure

in subjects and would be a tedious/time-consuming process (28%). 20% participants felt it would affect large community-based studies.

- Formation of a national network of investigators: 98.5% participants unanimously agreed that it was essential to form a national network of investigators with 76.7% participants recommending that an online network portal would be a good option.

DISCUSSION

Clinical trial investigators are one of the major stakeholders in clinical research. Due to limited networking among themselves, poor communication, lack of a forum for expression, and lack of direct dialog with the DCGI, their views and opinions have largely remained unheard with country’s regulatory authority. In the present survey, we intended to study the opinion of Indian investigators regarding the recent mandates issued by the DCGI for the conduct of clinical trials.

Key findings

This was the first survey conducted in Indian investigators to know their opinion about the recent regulatory guidelines introduced in our country. The survey attempted to capture the investigators opinion regarding the major regulatory changes introduced by the DCGI. Introducing central registration of ECs in India, one of the major changes in the Indian regulatory scenario was well accepted and received by investigators as evident from the level of agreement (90.1%) given to this mandate by participants. Similarly, the mandate of providing compensation to study related SAE (rule 122 DAB) was thought to be appropriate and essential by participants (76.8%). Another major regulatory change of introducing AV recording of IC process in India was disagreed by almost 50% of participants. The issue of introducing AV consenting of IC process was strongly debated with participants in agreement citing reasons such as legal protection offered to investigators and overall improvement in IC process due increased accountability. Participants in disagreement

Table 4: Reasons put forth by investigators on restricting number of trials handled by investigators

Reasons	Strongly agree (5) (%)	Agree (15) (%)	Neutral (4) (%)	Disagree (6) (%)	Strongly disagree (13) (%)
Increase oversight, responsibility of investigators	80	47			
Improvement in data quality		13	25		
Applicable if numerous trials in recruitment phase with investigator		33	25	17	
Counterproductive to hospitals with high volume of patients/orphan drug trials			25		23
Focus on investigator’s training, experience, skills, time management, infrastructure, efficient team			25	83	62
Restriction should be on number of subjects per trial	20				7.5
Decision should be with EC		7			7.5

EC=Ethics committee

with the mandate expressed that AV recording of consent process may cause anxiety and discomfort in patients along with sociocultural and patient confidentiality issues. They also said that it would be a time-consuming process and not possible for large community-based studies.

Interpretations and implications of the study

This was the first survey conducted in Indian investigators to know their opinion about the recent regulatory guidelines introduced in our country. An online survey was conducted in 2011 by Parikh *et al.*^[9] in various clinical research stakeholders regarding their perception of the clinical trial industry in India. This particular survey reported a lack of trained investigators and delay in regulatory approvals as major hurdles for clinical research in India along with the lack of trained staff, lack of awareness among general public, and unethical practices. Another online survey conducted by Jadhav and Bhatt to study the perceptions of clinical research professionals regarding the Ethics in Clinical Research in India reported IC process and documentation, empowerment of ECs, patient awareness on safety, and compensation rights as the major hurdles in conduct of Clinical Trials in India.^[10] In our survey, participants have emphasized on similar issues such as positive changes in EC functions brought about by central registration, ethical importance of providing compensation for study related SAE's, along with the hurdles faced in implementation of following AV recording of IC process in India thus reinforcing the fact that these are areas where clinical trial stakeholders need to focus their efforts.

The regulatory mandate of central registration received a general agreement with the participants, thus indicating the relevance of this mandate in structuring the ECs in our country. A survey to study the profile and role of EC members in Pune city conducted in 2009 had reported suboptimal understanding of ethical issues among the members along with the lack of formal training in ethics and comprehension of consent forms.^[11] A study conducted by ICMR^[12] had noted various problems with ECs such as the absence of legal experts, poor record keeping, and independence of members. Also, the establishment of a central registration system for ECs in India had been a long time recommendation.^[13] The justifications received in support of an agreeable response reflect the positive changes such as increased efficiency, responsibility, and accountability occurred in Indian ECs post central registration. A small proportion of participants, who disagreed felt that central registration is a challenge due to lengthy paperwork, and administrative hurdles in processing the application on account of geographical distance with the DCGI office.

A study conducted in South India on the effectiveness of IC process has highlighted various issues such as inadequate

information provided during the consent process, doctor's influence on subject decision capacity and poor literacy in trial subjects.^[14] Although the regulatory change of introducing AV recording of IC process received a high level of disagreement by participants, participants who agreed with the AV recording suggested that introduction of AV consenting will improve overall responsibility and accountability of investigators toward IC process. AV recording of IC has sighted advantages as well as hurdles. Advocacy of AV recording of IC highlights certain aspects such as safeguarding of all stakeholders in trials, the reliability of the IC process, increased transparency and improvement of IC process procedure and simplification of the IC documents. Major obstacles anticipated are infrastructure and sociocultural issues related to AV recording. AV recording will demand provision of separate space with minimum noise and equipment to record and store the videos. These requirements may be a challenge for investigators especially those in government hospitals. IC process in Indian patients is largely influenced by the sociocultural factors prevailing in our country.^[15] The sociocultural practices such as *ghungat* (veil of scarf) or the *burkha* practices for women prevalent in major Indian societies may not approve AV recording. Many patients may be apprehensive about discussing their disease on camera for fear of social stigma and maintaining subject confidentiality may be a significant hurdle. Thus, the relevance of AV recording of IC in India is strongly debatable, and same has been highlighted in our survey. With the recent regulatory guidelines, the DCGI accomplished a commendable task of bringing structure and stringency to the clinical trials scenario in India. However, the utility and implications of these guidelines with respect to our sociocultural environment needs to be assessed.^[16]

Provision of compensation for study related SAE's was thought to be essential by survey participants. Participants in agreement justified the mandate by saying it was patient's right to be compensated for study related SAE and investigator's moral responsibility to provide the same. It is also necessary to ensure that compensation guidelines are not detrimental to investigator-initiated research trials which are mainly conducted in resource-limited settings with a possibility of interventional studies becoming a monopoly of large pharmaceutical companies while investigators would be compelled to focus on observational studies.^[17]

Participants largely disagreed to the compulsion of including government hospitals as clinical trial sites. Survey participants who disagreed put forth that selection of clinical sites must be made by assessing the trial site performance along with experience, qualifications of the site team along with infrastructure quality of the trial site.

This consensus could be influenced by the fact that majority of participants were from private institutions. However, it is essential that DCGI initiates Good Clinical Practice training programs for government hospitals staff and provides funding for development of good infrastructure for conducting clinical trials.

The mandate of restricting the number of trials per investigator was equally agreed as well as disagreed by participants. Participants who agreed to a restriction on the number of trials handled by an investigator cited increased responsibility, oversight by the investigator along with the generation of good quality data. Considering the demands of clinical trials in terms of research infrastructure, the existing structure of health care system even if included may not ensure equity and may be counterproductive to clinical research in India.^[18]

Strengths and limitations

The survey was sent to 128 investigators from various therapeutic areas all over the country, and 73 investigators responded to it (response rate 57%). Investigators from different parts of India and from varied faculties such as cardiology, oncology, respiratory, and diabetes participated in the survey. This was the first survey conducted in India post introduction of new regulatory guidelines to gain an insight in the mindset of Indian investigators who are the crucial implementers of these guidelines. A major limitation of this study was a relatively small sample size as it was a pilot study. The survey also received a fair response rate of 57%. Also, our survey was restricted only to opinion and perceptions of clinical trial investigators. It is essential to study the same in a large arena of the clinical research community to have a nationwide consensus on the new regulations. Moreover, the survey had a large representation from private institutions as compared to government institutions which may have influenced some observations. We recommend similar large-scale surveys which will necessarily reflect the clinical research community's opinion on regulatory issues.

CONCLUSION

The response of the survey participants who are clinical trial investigators in India showed general acceptance, effectiveness, and anticipated compliance to the new regulatory guidelines. Stringent regulatory guidelines play a significant role in protecting the rights and safety of patients and developing quality research environment. The regulatory authorities and the clinical research community need to work in a cohesive manner

for effective implementation of new regulations. It is advocated that a right balance is achieved between stringent regulations and propagation of quality clinical research in our country.

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Conflicts of interest

There are no conflicts of interest.

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