Audio visual recording of informed consent process

Arohee Ketkar

The audio-visual recording of the informed consent process for patient participation in clinical trial is unique to India. As per the DCGI office order dated 19th November 2013, Audio Visual (AV) recording of the informed consent process has been made mandatory for clinical trials. The office order states that in addition to requirement of obtaining written informed consent, audio visual recording of informed consent process of each trial subject is required to be done while adhering to the principles of confidentiality. There are many advantages of audio visual recording of informed consent process. However it also poses several challenges. This article reviews the benefits of AV recording of informed consent and the challenges it poses to clinical research.

The informed consent in the context of clinical research is the process by which a subject voluntarily confirms his or her willingness to participate in a particular clinical trial after thoroughly understanding all aspects of the trial. Performing any research related procedure on an individual without obtaining his/her informed consent is a gross violation of regulations and GCP guidelines. As per the Schedule Y, in all clinical trials, a freely given, informed written consent should be obtained from each study subject. The investigator is obligated to provide all the relevant information about the study verbally as well as using a patient information sheet, in a language that is non-technical and understandable by the study subject. The subject's consent must be obtained in writing using an 'Informed Consent Form'.

As per the DCGI office order dated November 19, 2013, Audio Visual (AV) recording of the informed consent process has been made mandatory for all clinical trials. The office order states that in addition to requirement of obtaining written informed consent, audio visual recording of informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding of such consent is required to be done while adhering to the principles of confidentiality. This office order is in support to order dated October 21, 2013 from the Supreme Court of India which had highlighted the need for AV recording of the informed consent process. Further, ‘Draft guidelines on audio visual recording of informed consent process in clinical trial’ is still awaited. A visual tape recording of the consent interview is also recommended by United States Food and Drug Administration in case of illiterate participants who can understand and comprehend spoken English but are not literate.

Need to address key issues of the industry

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Practical challenges in implementing AV recording

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physically unable to talk or read and write. As per Indian Council of Medical Research Ethical Guidelines, in case of sensitive nature of the project or when written consent as signature or thumb impression is not possible, AV methods could be adopted with prior consent and adequate precaution to ensure confidentiality. Ethics committee (EC) approval is required for such procedures.

Advantages of audio visual recording

Over the past few years it has been alleged that Indian patients have been unfairly exploited for the benefit of the clinical research industry. Further, allegations have been made that vulnerable patients were recruited in clinical trials without proper informed consent. In India, where illiterate patients participate in clinical trials, mandatory audio visual recording of informed consent process becomes important for the protection of the patient’s safety and rights. The main idea and purpose behind audio visual recording of the consent process is to ensure that the clinical trial participants are adequately informed about all aspects of the clinical trial including risks, benefits, chances of failure of the Investigational Medicinal Product (IMP) to give intended therapeutic effect and to ensure that they have understood the details of the study including their rights, so that individual’s voluntary participation is ensured. Audio visual recording of informed consent can provide a documented proof that informed consent has been taken according to the stipulated rules and guidelines. In case of any dispute or litigation, audio visual recording of informed consent process can be used as evidence in the court of law.

The investigator needs to ensure that all essential elements of informed consent are discussed with the subject/LAR and their queries are answered satisfactorily. This ensures greater investigator accountability and overall improvement in informed consent process. The investigator can check subject’s comprehension by asking leading questions. If subject is able to answer them properly, it can be considered that subject has understood all the aspects of the clinical trial. Audio visual recording has made the process of informed consent, transparent and reliable. This will help improve the confidence of patients in clinical trials in general and informed consent process in particular.

Challenges in implementation

Stakeholders feel that there are practical challenges in implementing audio visual recording of informed consent process in clinical trials. Few stakeholders have expressed their views that audio visual recording of informed consent process should be made mandatory only in clinical trials of NCE/NME.

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Audio visual recording of informed consent unique to India

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It can be selectively implemented in clinical trials involving vulnerable population. Ethics committee can play a critical role in such case. The process of audio-visual recording of informed consent is unique to India. However, this uniqueness does not invalidate its utility. The utility of this process can only be ascertained by critically examining it from the perspective of all stakeholders.

Investigator perspective

Currently many investigator sites do not have the requisite infrastructure to conduct audio visual recording of informed consent. The lack of guidance on operational and logistical issues of managing the audio-visual recording process like the equipment to be used, definition of adequate resolution, where and how information should be stored, how confidentiality needs to be protected in audio visual context etc. has left room for ambiguity and inconsistencies in its execution. Some of the investigators find the process to be time consuming and burdensome.

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Patient perspective

A growing number of patients (20%-40%) are denying participation in clinical trials as they do not want to face the camera. The percentage can be higher in diseases like HIV, tuberculosis, breast cancer etc. where there is a social stigma attached. There could be several barriers in patients’ willingness to face the camera. It could be fear of leakage, tampering or misuse of the clip, feeling of intrusion to privacy, socio-religious factors and even poor self image on account of disease. The intent behind audio visual consent is to ensure that certain ethics are not violated in research, but sometimes one set of ethics can be in conflict with another. The consequence is that if patients are not willing to face the camera they stand to lose the potential benefits of participating in clinical research. Especially in diseases where there is no treatment available, the impact will be significant.

CRO and sponsor perspective

As per IESC statement dated November 22, 2013 the office order does not provide clarity about what studies

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Special safety studies may be essential

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Thus, special safety studies and special pharmacoepidemiological studies may be needed. The specific requirements of such studies should be based on the biologic characteristics of the SCCP. These studies may assess infections, immunogenicity, immunosuppression, teratogenic effects and malignant transformation as well as the in vivo durability of the associated medical device/biomedical component.

An independent data safety and monitoring process is required for all clinical studies. Complete adverse event reporting, safety update along with appropriate statistical analysis as per Schedule Y and ICH E guidelines should be made available for peer review committee.

Conclusion

CDSCO’s guidance document for SCCPs in adjunct with other applicable guidelines of India should be used for all the clinical trials of SCCPs. The guidelines however don’t give us solutions to many problems. Not all animal models may be applicable for SCCP. Also traditionally used randomized trials with placebo or comparators may also be not possible. The duration of the study and the follow up also may be arbitrary as we may not have sufficient experience with a particular condition/product. We may still be lacking in many aspects but a start in regularizing these studies is definitely a welcome step. We should look into similar guidance documents by other countries to serve as a reference point for us. As the science and research in this field evolves, the legislation and regulatory framework should also change to adapt the changes to come in future.

( Dr. Anuradha Kulkarni is senior associate - medical & regulatory affairs and Dr. Arun Bhut is president, Clariant Research Pvt Ltd)
Effect on recruitment
The experience so far shows that audio visual recording of informed consent process has slowed down recruitment at clinical trial sites. The reasons could be many like denial by subjects to face camera, increased workload at sites, cost implications and more clarity required on certain aspects of the process. Audio visual recording of informed consent process is an important step taken to safeguard the interests of patients. However it should not prove to be a deterrent to patient recruitment. As the process gets refined and investigators and patients gain confidence about the AV consenting process, patient participation in clinical research should get a boost.

Implementation of audio visual recording
Now that the requirement of audio visual recording of informed consent process is here to stay, all the stakeholders need to mend their ways towards implementation of the rule. The stakeholders need to amend their SOPs in order to incorporate requirements for audio visual recording.

CRO/sponsor representatives
For all the future studies, the availability of infrastructure for audio visual recording should be checked at the time of site qualification visit itself. The cost for running expense for recording and storage should be factored in while planning study level and site level budgets. The recruitment should be planned keeping in mind that 20%-40% of patients may actually deny participation on account of audio visual recording. CRO/sponsor may plan to take more number of sites than usual in order to avoid delays in recruitment. CRO/sponsor representatives need to redefine the expectations on monitoring of audio visual recording of informed consent process in a monitoring plan for the study.
Investigator sites should build infrastructure

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CRO/sponsor representatives need to train investigator sites on the expectations and the process of audio visual recording during investigator meeting or site initiation visit.

Investigator sites
Investigator sites need to build infrastructure for audio visual recording which includes a designated area free from disturbances, equipment to record informed consent process and equipment to preserve audio visual recording. It is important that investigator and study staff involved in audio visual recording of informed consent process are adequately trained and are delegated such responsibilities. This documentation should be maintained on the training and delegation log.

Investigator sites need to build infrastructure for audio visual recording which includes a designated area free from disturbances, equipment to record informed consent process and equipment to preserve audio visual recording. It is important that investigator and study staff involved in audio visual recording of informed consent process are adequately trained and are delegated such responsibilities. This documentation should be maintained on the training and delegation log.

At the beginning of audio visual recording, investigator should identify the protocol, the subject/LAR/IW and the language best understood by the subject, and study staff involved in audio visual recording before the discussion related to the clinical trial begins. At the beginning of audio visual recording, investigator should identify the protocol, the subject/LAR/IW and the language best understood by the subject. The investigator/designate must explain the study to the potential subject verbally, providing all pertinent information as per essential elements (purpose, procedures, risks, benefits, alternatives to participation etc.) and must allow the potential subject ample opportunity to ask questions. Informed consent is not an event but a process and it can happen in multiple sessions. In such a scenario, all such discussions should be recorded. Each session should begin with reference to the previous session so that different sessions can be linked together.

There should be a quality check of content of recording by a designated study person. Investigators will need to ensure controlled access to audio visual records to avoid any tampering and misuse. Audio visual recording files should be saved in a password protected folder with limited access. Investigator sites can prepare one subject specific DVD for each audio visual recording. The DVD should be labeled with study code, subject number, site number, study number, and date of recording.

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Ethics committees need to amend their SOPs

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Ethics committees need to amend their SOPs and need to ensure that audio visual recording of informed consent is followed in all clinical trials that they provide oversight on.

Audio visual recording of informed consent process is a step towards it. However stakeholders need more clarity on many aspects which are critical to ensure consistent implementation. Stakeholders need to amend their SOPs as per new requirements. It needs to be ensured that steps taken to safeguard patients should not act as a deterrent to patient recruitment and hence for conducting clinical trials in India.

(The author is Deputy General Manager, Clinical Operations, SIRO Clinpharm)

Ethics committees need to amend their SOPs

Ethics committees need to amend their SOPs and need to ensure that audio visual recording of informed consent is followed in all clinical trials that they provide oversight on. Sites may also keep a back up of audio visual recordings on an external hard disk. Investigator sites may delete audio visual recording from the recorder/computer once it is ensured that the recording is of adequate quality, right format, complete and that it is properly stored and archived.

Investigators need to convince the patient that the audio visual recording of informed consent process is mandated by law and is actually meant for their safety. The investigator will have to assure the patient about confidentiality maintained by the site, end use of this information and how it will be stored at site.

Ethics committees

Ethics committees need to amend their SOPs and need to ensure that audio visual recording of informed consent is followed in all clinical trials that they provide oversight on. The EC can use this as a tool to oversee the consent process at the site and direct the investigator in case of any shortcomings in the process.

Conclusions

Clinical research is the only way to find newer, cost effective and safer treatments to the diseases that are global and also the ones that are unique to this part of geography. India has 16 per cent of world’s population, 20 per cent of global disease burden and less than 2 per cent of global clinical trials take place in India. With growing incidence of endemic diseases and lifestyle diseases in India, it is important to have India representation in global clinical trials. India needs a robust regulatory framework that ensures that clinical research is conducted in an ethical and transparent manner.

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