

The challenges of remote audits or telework of non-clinical studies in Japan

Noriaki Katanozaka (Sekisui Medical Co.Ltd), Akira Yamazaki (Kyowa Kirin Co., Ltd.), Yoshiaki Hiraishi (Terumo Corporation), Terukazu Kitahara (Instem)



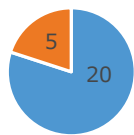
Introduction

The Covid-19 pandemic has also had a significant impact on institutional activities, GLP qualification inspections by monitoring authority and sponsored on-site investigations into CROs in Japan. The impact is that some work has been replaced with telework at the facility, and regulators and sponsors have switched part of audit from on-site to remote. This time, we conducted a questionnaire survey on remote inspections within JSQA. Based on the results, we will consider the implementation status and issues of remote audit in Japan. We also consider remote approval of records and documents in telework and ensuring the reliability of external computerized systems such as the cloud computing.

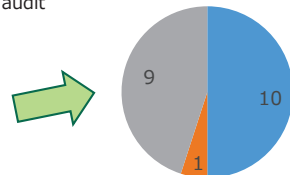
Questionnaire analysis

Remote audit

Experience of remote audit



Audit by monitoring authorities



■ Yes
■ No

■ Pharmaceuticals and Medical Device companies
■ CRO
■ No experience

Type of inspection (11 companies) by PMDA



■ Document - based Conformity Audit
■ GLP
■ GCP
■ Others

Supplier audit and monitoring for test facilities



■ Pharmaceuticals and Medical Device companies
■ CRO

Remote auditing has been already widely accepted under the Covid-19 pandemic. However, the scope of remote auditing is limited to document investigations. PMDA also conducts remote audits not only in GLP but also in other fields.

Advantage/Disadvantage/Problem

Perspective from Sponsors

advantage		disadvantage	
No need to consider travel time to inspection location	4	Even with video, there is a limit to the scope of what can be seen compared to an on-site audit.	2
Sharing documents prior to the audit will lead to efficient reviews during the audit period.	2	There is a limit to the number of documents that can be reviewed on the audit day.	2
Participation from multiple locations	1	If the document is not presented smoothly, it may have a negative effect on the sponsor's impression.	1

Perspective from CRO

advantage		disadvantage	
Audit programs can be easily arranged according to requests.	4	It is difficult to respond flexibly on the day of the audit	2
It is the same description as the second advantage from the sponsor's point of view described in the previous table.	2	It takes too long to prepare for the request.	2
It is possible that the time of preparing for the customer visits.	1	Limited amount of document can be viewed on the day of the audit.	1

In common opinion with the contractor and the CRO, there were many opinions that it was easy to adjust the inspection schedule because there is no need for the auditor to move to the location where the audit will be conducted.

As the second most common opinion, since document can be shared in advance, the time that was used for document review during the on-site audit can be allocated for question and answer sessions and discussions.

At many GLP facilities in Japan, raw data is paper-based data. In other words, the digitization of measurement data and experimental records has not progressed. Therefore, it takes a lot of time to scan them and create a PDF. From a Data Integrity perspective, it is necessary to electronic raw data and introduce electronic signatures used to approve electronic data, depending on the risk.

By taking such measures, it is expected that the reliability of telework and remote work will be built. There are still many challenges in migrating from raw paper data to raw electronic data, but a risk-based approach needs to be addressed to ensure the reliability of the data.

Usage of cloud computing in Japan

In Japan, suppliers are considering the use of cloud computing systems for GLP studies, but we believe that there are still risks in using them for GLP studies. The risks we consider include the following, but are not limited to;

- Communication with users, service suppliers, and data centers
- GLP education and training for staff working in service suppliers and data centers
- Electronic data archiving process



Conclusion

Onsite audits and remote audits have their advantages and disadvantages, respectively. It is expected that a risk-based audit style that combines the strengths of each other will be established in Japan as well.

Thus, remote auditing encourages us to digitize data and records, and to ensure the reliability of electronic data and records, which is also necessary from the perspective of data integrity. The operation of the computerized system that makes this possible is our challenge.