Conducting Remote Audits

INTRODUCTION

Pandemics, natural disasters, health or travel risks and travel restrictions are a few examples that can raise concerns for auditors and auditees' safety. In order to continue GxP obligations set forth by the Competent Authorities globally, Sponsors and Marketing Authorisation Holders (MAHs) can take a risk-based approach and decide on a case by case basis whether a remote audit is a feasible alternative to an on-site audit. There are both advantages and limitations to the remote auditing process that should be considered following liaison with all stakeholders.

ADVANTAGES OF REMOTE AUDIT PROCESS

In principle, an audit conducted remotely follows the same pattern and principles as for an on-site audit. The following are considered advantages of the remote audit execution:

Table 1. Advantages

Travel	a) Eliminates travelling where this is not feasible, or where there are risks associated with face to face meetings that could pose a risk for auditors and auditees' health or safety b) Can be conducted from almost any location c) Staff who are unable to travel can participate in the audit d) Easier to re-schedule audit dates if necessary, since travel is not a factor e) Reduces carbon footprint f) Decreases the burden in obtaining travel visa and other administrative problem
Oversight	a) More audits can be executed in a shorter time period due to saved travel time b) Several additional auditors can participate from several locations, or learn from such audits, for example auditor 'on the job' training c) Beneficial for targeted repeat audits, for example frequent oversight of and follow-up on Corrective Action and Preventive Actions (CAPAs)
Technical Solutions	a) Appropriate communication tools and technologies are becoming more widespread b) Encrypted document sharing platforms can be utilised to share confidential audit documentation efficiently and securely

CHALLENGES OF REMOTE AUDIT PROCESS

There are challenges and limitations that can be encountered during the preparation and execution of remote audits. The challenges which could affect the audit conduct may exist at different levels: company level, service level, project level and general areas.

While remote audits may not follow the traditional approach as an on-site audit, they can still offer a meaningful examination of compliance. Thanks to many common place technologies, conducting remote audits has become more effective and offers a potential solution where security, travel or other factors may impose restrictions upon traditional in-person and on-site audits.

Table 2. Challenges of Remote Audit Process

Communications and Technical Solutions	a) Need for robust and effective Information Technology (IT), such as phone, video camera, reliable internet connection, and sufficient screen resolution b) Lack of face to face personal close interaction can reduce the ability to build a rapport with the auditee c) Significant time zone differences should be considered
Document Sharing and Review	a) Some source data verification may be challenging depending upon confidentiality and data privacy b) Difficult to re-check documents in a timely manner, if for instance provided via screen sharing c) Burden of scanning large paper records can be onerous
Interview Sessions	a) Lack of facial and body language interpretation during a remote interview b) Sessions can be more challenging for non-native speakers c) Sessions with several interviewees may require additional considerations (e.g. it may be difficult to know who is talking and what is his/her role)
Facility Review	a) Lack of a three-dimensional view during virtual tour b) Unable to assess facilities at first-hand e.g. sample processing in a laboratory

EFFICIENT CONDUCT OF REMOTE AUDITS

Challenges and limitations, which could affect the audit conduct, should be prospectively identified and adequately assessed. A risk score system may be introduced by a Sponsor or MAH to identify where particular limitations impacting the execution of the remote audit could exist and these can be categorized as high, medium or low based on the company's internal processes, specific audit expectations and GxP requirements.

Specific considerations, tools and checklists can then be used in order to prevent or mitigate important and/or likely sources of limitations to the audit execution. The following points should be considered to ensure the audit is conducted as effectively as possible:

Table 3. Efficient Conduct of Remote Audits

Oversight	a) Adjust the audit agenda and durations to ensure all required topics and documentation review are covered without overly burdening the auditee
Communications and Technical Solutions	a) Consider which time zones need to be included, and how to maximise the overlap of availability b) The availability of robust IT system and supporting technology to ensure easy access to the documents and interviewees c) Perform tests of the agreed platforms to ensure the auditors and auditees can connect, exchange files in a secure manner and screen sharing and/or video is possible
Document Sharing and Review	a) Agree in advance how the documents will be exchanged during the remote audit process b) Allow time to reconcile document requests with the auditee
Interview Sessions	a) Ensure a clear and comprehensive agenda is accompanied with questionnaires and/or checklists to ensure all sessions, key topics and aspects of the audit are adequately assessed b) Prepare a complete list of personnel and their job titles attending the audit in advance, to allow the auditor to easily identify the auditee's role and his/her tasks during the interview sessions
Facility Review	a) Utilise advanced IT solutions such as high-resolution video device streaming to deliver virtual tour of facility

CONCLUSION

While on-site audits are considered the most robust approach, remote audits provide a viable alternative in circumstances where there are concerns for health, safety or restrictions to travel for the auditors or the auditees.

At ADAMAS, we are very conscious that when an on-site audit is not feasible our clients have an ongoing regulatory requirement for compliance oversight and travel restrictions can make this very challenging. ADAMAS is well-placed to assist with conducting audits and quality assessments remotely.

ADAMAS understand that remote audits may be unfamiliar to some, over the recent years our Consultants have gained wide experience with their conduct and successful delivery. We are adaptable and flexible and recognize that time zones may need to be considered, we can leverage our Consultants geographical localities on the American, European and Asian continents to mitigate these challenges and draw on their experience and knowledge to support you.

To find out more about what ADAMAS can do to support your audit program, please feel free to email us at:

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