



14th EBF Open Symposium
Science – Our Universal Language

Remote Inspections: Practical Considerations & Challenges from Industry

Robert Nelson, on behalf of the EBF

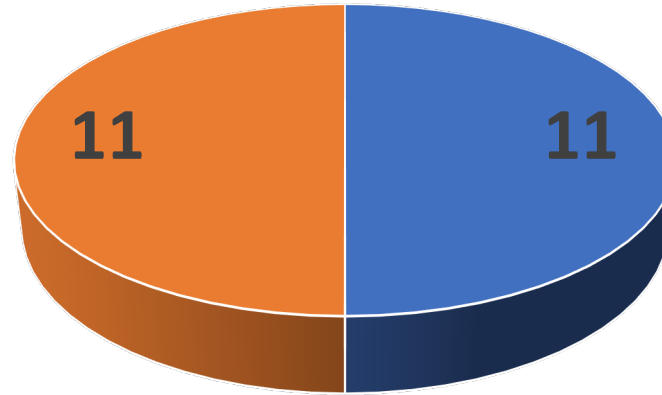
24-26 November 2021, Barcelona

Survey on Experiences with Remote Inspections

- Pre-meeting, we surveyed the members of the EBF community to take a temperature on experiences of remote inspections pre- and post-COVID
- Aimed to identify challenges faced, but also opportunities for the future

Respondent Affiliation

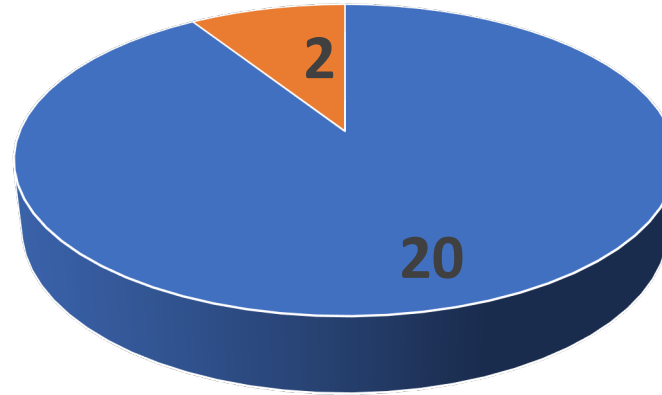
➤ Question 1: I am...



■ CRO ■ Pharma

Pre-COVID experience of remote inspections

- Question 2: before 2020, (pre-COVID) we had experience with remote inspections



■ No ■ Yes

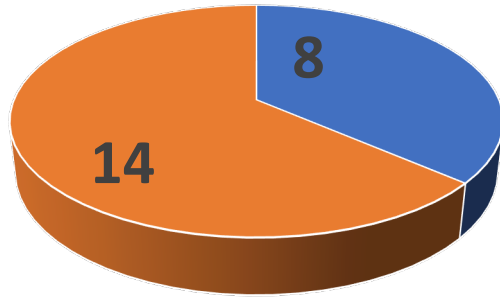
Yes: both CRO

Pre-COVID experience of remote inspections

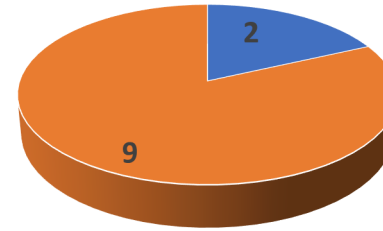
- If yes, from which authority(ies) & can you share the type of inspection
 - NMPA: Clinical Trial Data Verification Inspection
 - WHO: Desk Assessment
 - o sponsor submission of Clinical Trial/specific application allocating to assess CRO processes and QMS at same time

Post-COVID experience of remote inspections

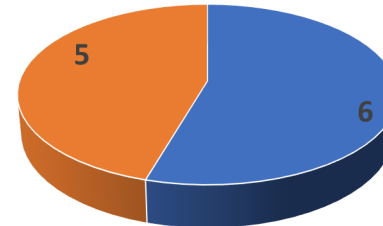
- Question 3: since 2020 (With-COVID), we have experience with remote inspections



■ No ■ Yes



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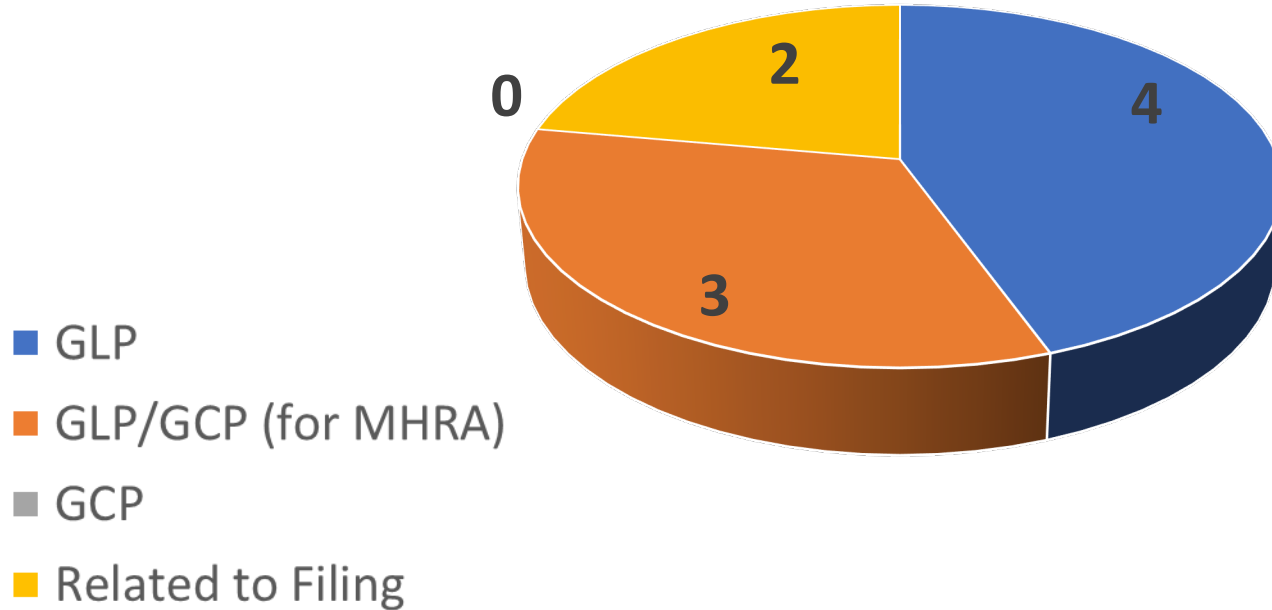
Pharma

Post-COVID experience of remote inspections

- If yes, from which authorities
 - MHRA
 - FDA
 - ANVISA (Brazil)
 - WHO
 - Standards Council of Canada
 - Danish Medicines Agency (DKMA)
 - Local HA

Post-COVID experience of remote inspections

➤ If yes, can you share the type of inspection



Post-COVID experience of remote inspections

- If yes, can you share the type of inspection
 - MHRA: GMP
 - MHRA: GLP/GCP
 - FDA: Remote records review
 - FDA Bioresearch Monitoring (BIMO) for BA/BE
 - ANVISA: BE studies
 - WHO: Desk Assessment
 - Standards Council of Canada: GLP continued accreditation
 - Local HA: GLP “Hybrid inspection”

Opportunities for remote inspections

- Question 4: please highlight the **top 3 opportunities** you see related to remote inspection

Opportunities for remote inspections

➤ Communication

- Better opportunity to communicate internally and coordinate to response to request
- Good opportunity to discuss with inspector (Teams/Zoom)
- Human interaction is different; should be taking the time to truly connect with inspectors and also with internal auditees, establishing trusted relationship, understanding their needs and the process for transparently cooperating and sharing of requested information. Opportunity for creating an environment of trust, collaboration and communication.

Opportunities for remote inspections

➤ Dynamics of the inspection

- Remote inspection provided the opportunity to make sure the inspection and approval for the drug would not be delayed even under the pandemic situation
- Planning for the inspection by the HA is more upfront, with a more defined agenda allowing us the opportunity to plan
- Time between announcement and actual start of inspection allowed for proper preparation
- Difference in time zones between us and inspector limited the time per day for the actual inspection but provided more room for day-to-day preparation / wrap-up activities
- Easy to adapt agendas to schedule virtual Q&A meetings (from anywhere, home or office)

Opportunities for remote inspections

➤ Dynamics of the inspection

- To some extent there is more time to consider responses and gather information due to the format, than in a face-to-face situation where an immediate response is needed
- In general, less stressful atmosphere
- Have time to prepare documents
- Don't have to physically accommodate the inspector
- Inspector was given live video tour of facility (with opportunity to ask questions)
- More focus on quality process and less on 'study'

Opportunities for remote inspections

➤ Dynamics of the inspection

- Inspector had more time and requested more documents to review
- More focus on data integrity/audit trail
- All types of assessments/inspections are technically possible (from visual inspection of a process/equipment to records review) with almost no limitations, including review of electronic source data in electronic systems and interviews with staff
- Could apply to low or medium risk facilities thus creating a more flexible overall inspection program
- Potential involvement of sponsors and other parties (cross inspection by different countries); Some countries have mutual agreement for inspections and sharing outcomes

Opportunities for remote inspections

➤ **Efficiency & Cost/Time/Carbon Footprint Reduction**

- Efficiency and time optimization (e.g., during the review of documentation related to organizational aspects)
- It reduces the costs
- Reduced travel
- No travel (advantageous to budget and carbon footprint)
- Less traveling

Opportunities for remote inspections

➤ **Efficiency & Cost/Time/Carbon Footprint Reduction**

- Scheduling is more flexible and faster, long journeys are avoided. More inspection can be carried
- It will save time and cost for the inspectors compare to the onsite inspection
- When tools and technologies exist for sharing documents, conducting interviews and doing live tour/live streaming and assessment of a technical process, remote inspection allows for saving inspection travel time for inspectors and indirectly fees for the facility to be inspected

Opportunities for remote inspections

➤ e-Environment

- Digitisation of documentation is accelerated to a paperless lab, processes become more efficient.
- Provide adequate technical infrastructure for both, the actual interviews as well as for a virtual lab tour
- Improvement in electronic records management
- Encourage to continue transferring processes to paperless systems
- Improving site-wide WiFi connectivity
- Highlights the importance of an electronic labnotes system

Challenges for remote inspections

- Question 5: please highlight the **top 3 challenges** you see related to remote inspection

Challenges for remote inspections

➤ Documentation

- All paper record must be digitalized (time consuming)
- Enormous amount of pre-requests between the time of announcing the remote record review (RRR) and the actual start of the RRR (approx. 3 weeks)
- A part of the data files (usually excel) had to be provided in a certain format which required a lot of editing & QC-checking.
- More complicated to share paper documents
- Paper-based documentation needs to be scanned and uploaded to a secure server
- Volume of the records to be scanned
- Time taken when records are paper to get them ready for upload to the HA

Challenges for remote inspections

➤ Documentation

- Paper based documentation are almost impossible to present to inspectors remotely
- Time taken having to issue documents (e.g. SOPs) to the inspector
- Ability to cross reference and link up different records is more challenging
- Paying attention to the confidentiality of records; sharing different screens/systems screens and views is challenging and necessitate good master and controls of technology

Challenges for remote inspections

➤ Infra-structure

- Secure platforms to share confidential information
- Process flows are easier to visualise on site
- Difficulties during remote site tour to show rooms and equipment (WiFi connectivity issues)
- Technical infrastructure set-up challenging and resources needed
- Identify a better tool for the virtual meeting would be significantly improve the quality of the communication and reduce the time of troubleshooting for technical issues
- Technical difficulties in recreating a tour of the facilities
- Requires update of AV equipment and training of using these devices

Challenges for remote inspections

➤ Infra-structure

- Additional resources to deliver requested information from Archive (scan & upload)
- Remote meetings may pose a technological challenge if Wi-Fi/connectivity issues are experienced by attendees (both inspectors and participants /host)
- ‘Physical’ processes more difficult for inspector to review (i.e. Sample Management / Sample Storage)
- Stability of live streaming video/stability and clarity of images/ quality of audio especially during live tour of the lab etc. so that reg agencies can adequately assess the state of bioanalytical laboratory and perform technical assessment /witnessing of an inspected process with least disturbance or bias.
- May not be easy to see all details from distance. Close-up shots maybe requested; should be ready to zoom in on equipment labels or zoom out to present more global views/operations of the lab.

Challenges for remote inspections

➤ Timing & Time Zones

- It is a challenge to close the inspection on the proposed day (always more items to review)
- Remote inspections take longer to conduct than on-site
- Better planning with the agenda and timeline. For some of the inspections, the inspector not have the planned date when the inspection could be finished since it will depends on the progress of the document review. If can have better planned with the fixed dates for the inspection could be helpful
- Easy for inspector to extend the inspection

Challenges for remote inspections

➤ Timing & Time Zones

- The inspection schedule must be planned taking into account the time difference between countries.
- Inspection program needs to accommodate time zones, breaks, duration
- Time difference between Auditor's country and Auditee's country making interviews / interactions difficult
- Time zone difference which makes both inspectors and company very challenged during the inspection and will need longer time to complete the inspection

Challenges for remote inspections

➤ Communication

- Communication is definitely more limited, with larger inspection teams (more than 3 people)
- Cannot inspect the physical facilities / labs (virtual tour is not equivalent)
- There is no direct F2F interaction with the auditees and limited opportunity for follow-up discussions
- Barrier from the Communication, not able to see the same record together like the onsite inspection, may have some misunderstanding on the issue discussion and need more time for the clarification
- Questions and requirements can sometimes be misinterpreted during remote inspections

Challenges for remote inspections

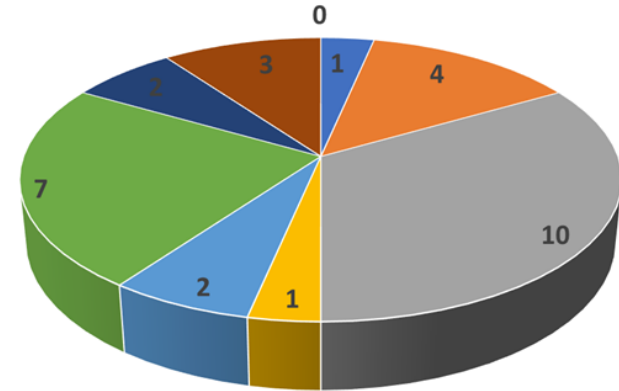
➤ Communication

- Less opportunity for feedback from inspector and discussions around findings
- Less opportunity to ask questions of the inspector, for items which didn't make it into the inspection report
- We should make sure that responses to questions raised are obtained clearly, complete and well understood so no bias is introduced at the time of issuing inspection findings
- Listening at live streaming or interviews along with remote review of several uploaded PDFs or electronic records during long hours of inspection may create a tiredness/mental fatigue from inspector's side. Difficult to notice; should be regularly taking the pulse on how the inspector is doing/feeling. Taking care of the human touch.

Opportunities / Challenges for remote inspections

Question 6: if you don't like writing in above questions..... highlight if you agree with following statements. I believe that remote HA inspection:

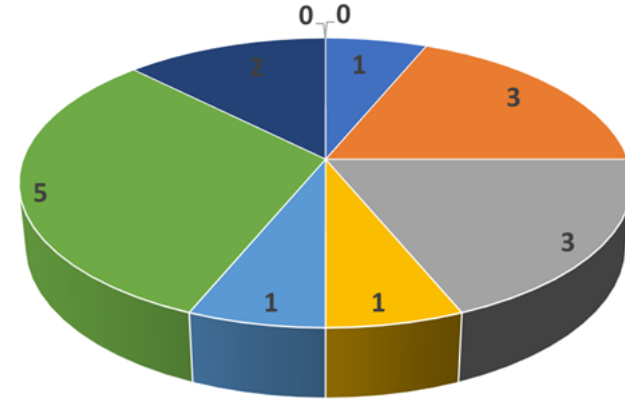
- a) give equal opportunity for discussions compared to on-site inspection (1)
- b) have made our life more difficult (4)**
- c) have the potential of raising the bar due to lack of open discussion on potential findings (10)**
- d) have made discussion opportunities more easy (1)
- e) should become the norm after COVID (2)
- f) should become an exception after COVID (7)**
- g) has changed the way we operate internally wrt to documentation (2)
- h) allow better preparation prior and during inspections (3)
- i) I have seen citings during remote inspections which I would not have expected during on site inspections (0)



Opportunities / Challenges for remote inspections

Question 6: if you don't like writing in above questions..... highlight if you agree with following statements. I believe that remote HA inspection:

- a) give equal opportunity for discussions compared to on-site inspection (1)
- b) have made our life more difficult (3)**
- c) have the potential of raising the bar due to lack of open discussion on potential findings (3)**
- d) have made discussion opportunities more easy (1)
- e) should become the norm after COVID (1)
- f) should become an exception after COVID (5)**
- g) has changed the way we operate internally wrt to documentation (2)
- h) allow better preparation prior and during inspections (0)
- i) I have seen citings during remote inspections which I would not have expected during on site inspections (0)

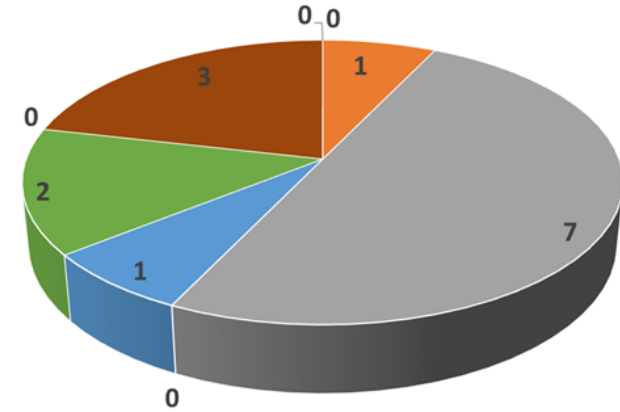


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Opportunities / Challenges for remote inspections

Question 6: if you don't like writing in above questions..... highlight if you agree with following statements. I believe that remote HA inspection:

- a) give equal opportunity for discussions compared to on-site inspection (0)
- b) have made our life more difficult (1)
- c) have the potential of raising the bar due to lack of open discussion on potential findings (7)**
- d) have made discussion opportunities more easy (0)
- e) should become the norm after COVID (1)
- f) should become an exception after COVID (2)**
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- h) allow better preparation prior and during inspections (3)**
- i) I have seen citings during remote inspections which I would not have expected during on site inspections (0)



Pharma

Opportunities / Challenges for remote inspections

- Remote inspections are (most likely) going to play a significant role going forward:
 - How do we better prepare ourselves to make the most of the opportunities?
 - And to address the challenges?



Acknowledgements

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Contact Information

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