

# EIGHTEEN MONTHS INTO REMOTE HEALTH AUTHORITY INSPECTIONS: LEARNING TOGETHER

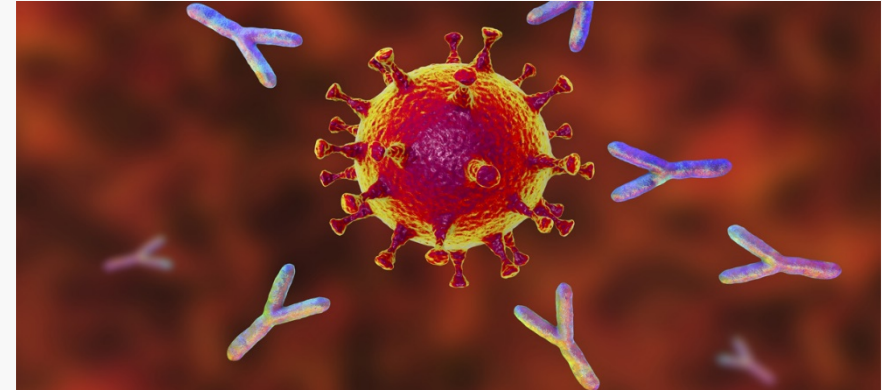
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Iain Love, Charles River Laboratories, Edinburgh  
Science - Our Universal Language, 24 Nov 2021,  
European Bioanalysis Forum Open Symposium,

EVERY STEP OF THE WAY

# REMOTE INSPECTION BY MONITORING AUTHORITIES

- Circumstances that have led us to where we are today
- Goals of a remote inspection
- Share experiences of Pre-Inspection and Inspection Phases
- Discuss challenges and learnings
- Future Perspectives



# REMOTE INSPECTION BY MONITORING AUTHORITIES

- Several GXP compliant Safety sites in differing geographies
  - USA, Canada, UK, France, Netherlands....
- All familiar with the responsibilities, rhythms and requirements of inspection
- 30 Jan 2020 WHO: *“Public Health Emergency of International Concern”*
- 38 Countries introduced travel restrictions in February 2020
  - Shut-down, lock-down, shelter-in-place, red-list, green-list, tiers, phases, social distancing...
- Immediate, drastic changes required to professional lives
  - UK Gov, 23 March 2020, *“You must stay at home”*

# REMOTE INSPECTION BY MONITORING AUTHORITIES

- How do we continue to meet our professional obligations?
- Immediate consequence: pause and recalibrate
  - In-person inspections delayed but for how long?
  - Patient care and monitoring of Covid prioritised

## *Mater Artium Necessitas -*

Remote HA inspection to become the (temporary?) new normal

- UK MHRA GLP Inspection March 2021
- UK FDA Remote Record Review Nov 2020

# REMOTE INSPECTION BY MONITORING AUTHORITIES

- Goals of a remote HA inspection = goals of an in-person HA inspection

*Evaluate the integrity of the data submitted to health authorities, protect patient safety, and assess adequacy of site/sponsor quality systems to achieve the same*

- Inspection outcomes should be consistent
- Practicalities transposed from the test facility/site onto a virtual platform to drive inspection continuity
- Pre-inspection, during inspection
- Successes measured by outcome

# PRE-INSPECTION PHASE

## Remote Inspection by Monitoring Authorities

- Familiar first contact process notwithstanding the need for remote access
  - In case of FDA first contact, MHRA were also informed for clarification
- Collaboration software platform selection
  - Comes with familiarity and security/ownership considerations
  - Trial run of software and video/suite
- Studies identified and agendas set consistent with in-person inspection though less defined past Day 1
- Expanded list of colleagues on stand-by



# PRE-INSPECTION PHASE

## Remote Inspection by Monitoring Authorities

- Document list requested in advance of inspection
  - Lengthier than an in-person inspection
  - More studies than “normal” and more supporting information
  - Management of “what-if” scenarios
- Significant digitization effort required: paper data, log-books, calibration records...
- Significant number of prep-days to de-archive and make available digital documents – burden above in-person inspection
- Data disposition
  - Assurances that data would be deleted after the inspection
  - Affords inspectors extra time with data outside of inspection schedule

# INSPECTION PHASE

## Remote Inspection by Monitoring Authorities

- Difficult to generate free-flowing discussion in the on-line space
  - Low level technology interruptions
  - Wrong people in the room to talk to specific questions
  - Dead air
- Raw study data shared ahead of inspection
  - 'Pre-inspection' paradigm has some positives
  - Increased opportunity of miss-interpretation
  - Increased risk that dialogue and discussion become a defense



# INSPECTION PHASE

## Remote Inspection by Monitoring Authorities

- Subsequent days not following agenda agreed in daily closing meeting
  - Difficult to arrange staff availability
- Each inspection/RRR required one unplanned extra day
- Adapting to more complex inspection landscape e.g. Data Integrity focus
  - Dialogue more scientific than in past inspection cycles
  - More detail oriented in the approach
- Facility tours went well
  - A focus in the preparation phase

# THINGS CAN GO WRONG!

Expect the unexpected



Prof Robert E Kelly keeps his cool during an interview about South Korean politics when his two children interrupt him, live on air, on BBC World News. Photograph: BBC News

 **Hold on**

Looks like something went wrong. We're trying to get you back into the meeting.



# MAIN CHALLENGES OBSERVED

## Remote Inspection by Monitoring Authorities

- Digitization of documents and upload to collaboration platform
- Format and familiarisation with software/tools
- Difficult for meaningful, detailed agenda
- Account for practicalities of time-zone differences
- Remote personnel require access to site and site infrastructure
- Laboratory tour arrangements
- Very likely to take longer than an in-person inspection

# LEARNING TOGETHER – PRE-INSPECTION

## Remote Inspection by Monitoring Authorities

- **Preparedness is Key – have a plan**
- Software, Platform, and Tools
- People – assign roles, ensure (just-in case) availability
- Ensure logistics are agreed a-priori
  - Ordered and categorised document repository and responsible person
  - IT contact and “runner” on standby
  - Walk throughs and plan for execution agreed before inspection opening meeting
- Agenda set
  - Time for bio-breaks, review sessions
  - Power the daily opening and closing meetings

# LEARNING TOGETHER – EXECUTION

## Remote Inspection by Monitoring Authorities

- Limitations of the on-line environment
  - Does not allow for free flowing discussion
  - Cannot easily build rapport
  - Cannot ‘read the room’ as naturally as an in-person group setting
- Important that good on-line etiquette is observed
  - Cameras on, Microphones off
  - Allow space for all to contribute and circle back to participants
  - Manage the clock
- Power opening and closing meeting to reset agendas and update doc request

# PERSPECTIVES ON THE FUTURE

## Remote Inspection by Monitoring Authorities

- Remote inspection has shown it can work and be a positive experience
- Inspectors/inspected feel comfortable that the same outcomes can be achieved compared to an in-person inspection
- Eighteen months of experience have shown that extra time and care is required
  - Consider more time allowance for fully remote inspection
- Preparedness is key and can bring positives
- Remote inspection shouldn't replace in-person inspection
  - Another tool in the inspectorate toolbox
  - A blended model should be a net positive

# REMOTE INSPECTION BY MONITORING AUTHORITIES

## Summary

- Challenging period that has brought us to remote inspection
- Industry and inspectorate have risen to the occasion
- Shared challenges, experiences and learnings from remote inspection cycle
- **Preparedness is key**
- Reflect and refine after each inspection
- Future looks like a hybrid of fully in person, fully remote and blended approaches

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# Thank you

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**[lain.love@crl.com](mailto:lain.love@crl.com)**

**Charles River Laboratories, Edinburgh**

**Website: [www.criver.com](http://www.criver.com)**