Remote Inspections & MHRA Innovation
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An “Unprecedented” Year
March 2020 Pandemic halted routine on-site inspections:
- Transformation of inspection model to remote
- High-risk or Covid-19 support inspections prioritised
  https://www.gov.uk/guidance/guidance-for-industry-on-mhras-expectations-for-return-to-uk-on-site-inspections

Challenges
- Covid-19 guidance & managing clinical trials:
- Vaccine & treatment inspection priorities
- EU Exit
Pre-Pandemic Remote Inspection Approaches

Majority of MHRA inspections on-site:
• GCP ‘Day 1’ office-based assessments
• ‘Main’ inspection in person
• Office based assessments for IAG cases

• Prior to pandemic, increasing levels of pre-inspection requests across GxPs. For GCP included:
  – Dossier
  – Procedures
  – Safety listings
  – Deviations and CAPA review etc.

GCP Inspections in a Pandemic

• Pragmatic approach implemented, reducing burden wherever possible

• Accommodates ‘inspectees’ working remotely as well as inspectors

• Inspection Reports still issued:
  • Critical inspection findings raised across GxPs demonstrating effective remote approach

• >30 GCP inspections conducted to date
Logistics & Challenges

- Organisations notified as normal (unless triggered short-notice)
- Any pre-inspection documents requested & reviewed as normal
- Modified requests & dossiers ensuring needs of inspection scope are met
- Inspection scope often narrower than on-site, directed by risk
- Inspections take longer (often)
- Technical challenges!
- Inability to ask ‘real-time’ Qs
- Rapport building
- Visuals: Inability to easily assess state of premises/ equipment/ facilities

Industry Views

Diverse views on flexibility – some sites appreciated; others felt it extended on-site approach
Supports health & safety of the company staff
Allows for greater flexibility with work schedule of inspectees
Potentially remote inspections may warrant delaying an on-site inspection, or reduced scope of on-site – seen as positive
Motivation to continue standards of compliance even in extreme change
Hybrid Inspections & the Future

- MHRA operating ‘Critical’ and ‘Covid-19 support’ required inspections on-site only
- From 29th March hybrid approaches continues, on-site if required
- Overseas inspections & NHS on-site routine are paused

**Focus remains on areas of risk**

- Inspection areas previously considered impossible remotely, have been challenged with successful outcomes…
- Remote BE inspections taken forward into current ‘routine’ ways of working
- Remote investigator sites

What is ILAP? Innovative Licensing & Access Pathway

- Opportunity to think and practice differently after EU exit
- The ambition of ILAP is to deliver safe, early and financially sustainable patient access to innovative medicines
- Key aspect of ILAP is the partnership between the MHRA, NICE and Scottish Medicines Consortium (SMC)
- NHS-E and in Scotland are closely engaged, along with the Accelerated Access Collaborative and other UK health system partners including HRA & NIHR
Innovative Licensing and Access Pathway: ILAP

- A new medicine designation allows Innovation Passport to be awarded

- **Target Development Profile** (TDP) creates a unique UK roadmap, using the ‘toolkit’ & providing a platform for sustained multi-stakeholder collaboration

- Built-in flexibility, with multiple entry points along the pathway (non-clinical data → clinical trials)

- 4 products piloted pre-launch on 1st Jan 2021
- 12 Innovation Passport applications in first 2 months
  

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Enabling Regulator: The Toolkit

- Adaptive inspections
- Centre accreditation
- Novel CT methodology & design support
- Common medicine & device trial design
- Coordinated approvals process for co-developed medicines & IVDs
- CPRD assisted recruitment in clinical trials
- Rapid Clinical Trial Dossier pre-assessment service
- Certifications
- CPRD control groups
- Enhanced patient engagement
- Continuous benefit-risk assessments that integrate real-world evidence
- New licensing procedures:
  - Rolling review
  - Accelerated timetables for marketing authorisation, flexibilities
- International options
  - FDA Orbis
  - ACCESS
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