Remote Inspections Gain International Traction

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Remote inspections of clinical trial sites will continue but not completely replace in-person efforts, according to **a new report** from the International Coalition of Medicines Regulatory Authorities (ICMRA). The report further says that such inspections remain challenging and more time consuming, and are even impossible in some scenarios.

Fran Ross, Managing Partner, Lucid GxP Consulting

The report also found there are no universal remote best practices in place, yet and there have so far been no notable differences in inspection results when compared to in-person inspections.

During the COVID-19 pandemic, international regulatory authorities adapted their inspectionapproaches to ensure regulatory oversight of GxP activities (such as Good Clinical Practice [GCP], Good Manufacturing Practice [GMP], Good Laboratory Practice, etc.), the ICMRA report notes. “Due to restrictions to protect public health, regulatory authorities utilized digital technologies, such as video conferencing software and devices, to enable continuity of compliance oversight,” the report says.

The ICMRA COVID-19 group set up a working group to review the adaptation of both GCP and GMP inspections during the COVID-19 pandemic to remote approaches. The working group had representatives from the U.S. Food and Drug Administration, European Medicines Agency, Health Canada, Swissmedic, HPRA Ireland, AEMPS Spain, ANSM France, PEI Germany, MHLW/PMDA Japan, TGA Australia, ANVISA Brazil, HSA Singapore, the World Health Organization, and Saudi Food and Drug Authority.

Given the growing prevalence of remote inspections, it’s incumbent upon regulated entities to conduct their own mock inspections and include a test of remote access along with sufficient technology support, Fran Ross, managing partner with Lucid GxP Consulting, told a forum sponsored by Veeva earlier this month.

Regardless of inspection type, each trial master file (TMF) must be kept up to date with audit trails. It's "more critical than ever to post TMF records with immediacy," Ross says.

She's also a big advocate of a risk-based approach to TMFs. "Remember that it's Good Clinical Practice (good), not Perfect Clinical Practice," she notes.

Another expert tip: Leverage the magic of metadata. "eTMF systems provide a wealth of information," she says.

Ross broke down the components of risk-based TMP management into four sections:

- Assess: Find and stratify high-risk records and processes; plan measurements.
- Test: Activate the TMF risk management plan.
- Learn: Measure the impact.
- Celebrate: Publicize results; celebrate wins and lessons.

A risk-based approach to TMF compliance will only become more vital as "the clinical trial landscape evolves and trial complexity increases," Ross says.

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