Webinar Q&A

Mock Inspections: A Critical Tool To Ensure Inspection Readiness

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Questions submitted by audience participants.
Responses provided by Kristen Bennett.

Q1) What is your experience with storyboards to use during an inspection, and does Avoca have a template?

Storyboarding a project's significant risks and issues that may be highlighted during an inspection is a leading practice for inspection preparation. Developing storyboards allows the project team to proactively identify the most significant issues and address them. Storyboards also allow the entire team to have a common understanding of the issue and the actions taken in effort to discuss these issues if they come up during an inspection.

Avoca does have a Storyboard template in the AQC Knowledge Center, accessible by Avoca Quality Consortium (AQC) Members.

Q2) Has Avoca seen any areas where Clinical Operations and Quality Assurance can do better in terms of partnering to prepare for inspections?

Clinical Operations and QA should work together on inspection preparation that includes but is not limited to: storyboard creation, inspection interview training of the project team, reviewing the Dos and Don'ts of inspection interviews, reviewing most challenging questions, and conducting Mock Interviews. Also, they should work together on ironing out the logistics of hosting the inspection.

Q3) Is there any data to suggest that just-in-time inspection training is better than regular, periodic training on inspection readiness?

While Avoca does not have data to suggest that just-in-time inspection training is better than regular periodic training on inspection readiness, most data regarding the best ways to learn suggests that just-in-time training is most efficient since it allows higher productivity and better absorption of information due to its timely nature. Inspection Readiness Training is a bit different due to the dynamic nature of a clinical trial and the need to proactively train for inspections to ensure that the tasks are completed in real time. Teaching and training your staff about inspection readiness prior to the inspection announcement allows staff to absorb and understand the knowledge while also providing the ability to deploy the information learned during the lifecycle of the study in an effort to be ready for when an inspection is announced. Therefore, by breaking down inspection readiness activities into just-in-time learning activities as reminders of what documents need to be stored and when, good documentation practices, etc., you are reminding your staff of how their day-to-day job can affect the outcome of a potential regulatory inspection.

Q4) Can you provide examples of "feedback loops" – updated SOPs, updated study plans, or active action items?

A feedback loop in Inspection Readiness occurs after a lesson is learned regarding a Storyboard process that was utilized by "Team A" to ensure the lesson learned is provided to "Team B", since they are preparing for an inspection as well. This could be a positive lesson learned in which Team B is informed of a helpful process that is critical for inspection preparation or it could be a negative lesson learned in which the process may need to be modified prior to Team B utilizing it.

Q5) What is the scorecard that you referred to?

The Scorecard reference was regarding the utilization of a Scorecard template as a tool to use for your periodic screenings and health check activities throughout the lifecycle of the study. The scorecard can be used at regular intervals by study teams to ensure activities/documentation required for the state of the study are complete. Avoca is currently updating our current tool, Sponsor and CRO Functional Inspection Preparation Checklist (INSP 02), to function as 1 tool to be used throughout the life cycle of the study instead of 1 tool to be used as one-off completion. The scorecards or dashboards show the current status of the key inspection areas and highlight those that may be at high risk for not being inspection ready.

Q6) We have reached a point where we feel inspection ready; how soon should mock inspections began?

Mock Inspections are typically scheduled 6 to 9 months prior to a regulatory submission. Being proactive is key, so if you feel as though your inspection ready and have plans for a regulatory submission in the near future, a mock inspection would be beneficial. That will provide time for the mock inspection to be conducted, the mock inspection report to be written and delivered, and time to action the observations.

Q7) Would you be able to provide a checklist of all documents that are generally compiled and QC'd during inspection readiness activities? Would you be able to guide us on where to locate this document or checklist?

Yes, there is an Avoca tool called the Sponsor and CRO Functional Inspection Preparation Checklist (INSP 02) that is a tool built from leading practices to prepare for inspections with various Health Authorities, accessible by Avoca Quality Consortium (AQC) Members in the AQC Knowledge Center.

In addition, the AQC Knowledge Center has a specific section for Inspection Readiness that includes tools and templates to utilize. This section of the AQC Knowledge Center is broken down into 4 main phases. Ongoing GCP Compliance, Inspection Preparation, Inspection Management, Inspection Follow-up.

It is worth noting that there is also an Inspection Readiness Grid that provides Agency Inspection Experiences by topic area.

Q8) What is the average time of a regulatory inspections?

Regulatory inspections are typically announced 1-3 months after regulatory submission. A typical regulatory inspection is 4-7 business days.