



WINNING THE CLIN OPS SUPER BOWL

REGULATORY INSPECTIONS
FROM THE CLINICAL
OPERATIONS PERSPECTIVE

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AGENDA

Best Practices Before, During and After Sponsor Inspections

- Team Try-outs & Early Practices
- Final Pre-game
- During the Game
- Post-Game

The Latest in Common Inspection Findings

- Key FDA and EMA Sponsor Inspection Findings



Before the Game: Team Try-outs

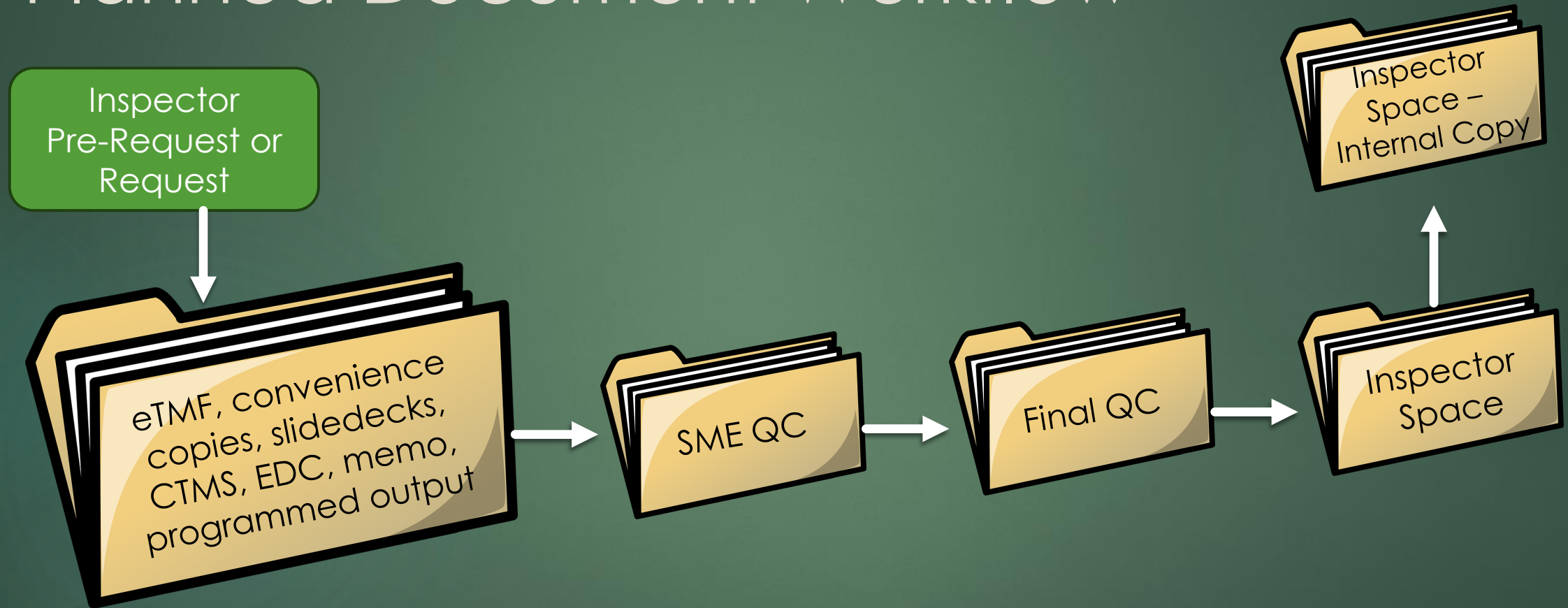
- ▶ Mock Inspection
 - ▶ Ideally prior to DBL and as early as feasible (risk is staff turn-over)
 - ▶ Good chance to pressure test the players in their positions
 - ▶ Ensure eTMF SMEs available
 - ▶ Consider SMEs and back-room assistance + overflow room assistance for Requests
 - ▶ SMEs for content QC vs. final QC
- ▶ Discuss vendor strategy for whether any vendor team members should be on-site or available remotely (CRO/vendor budget for inspection support?)
- ▶ Author/complete any CAPAs as a result of the mock inspection

Before the Game: Early Practices



- ▶ Cross-functional communication is key: QA, Clin Dev, Drug Safety, Biometrics, Data Management Regulatory, IT
- ▶ Storyboards (Issues/Processes)
 - ▶ Maintain storyboard list from the beginning of the study
 - ▶ Consider slidedeck presentations on complicated processes/issues
- ▶ Discuss the use of convenience copies of documents, depending on:
 - ▶ Your SOPs
 - ▶ How regulators will access docs during the inspection
 - ▶ How efficient you are at working within your eTMF (understand bulk download capability)

Before the Game: Planned Document Workflow



Before the Game: Final Pre-Game

- ▶ Set the expectation that it will be “all-hands on deck” and long hours during the inspection days
- ▶ Finalize and train SMEs on study plans and storyboards (including vendor SMEs)
 - ▶ Understand process for Requests that get passed through to vendors
- ▶ Finalize plan for any convenience copies of documents
- ▶ Finalize any slidedeck presentations that will be provided to Regulators
- ▶ SME’s practice interview sessions,
- ▶ Logistics run-through (game day food!)
- ▶ Tech run-through
- ▶ Get a good night’s sleep!



During the Game: Communication

- ▶ Use internal Chat application for Clin Ops-specific conversations
- ▶ Appoint a back-room Clin Ops lead that assigns the Requests
 - ▶ Separate, shared online tracker for requests assigned to Clin Ops
- ▶ If CRO/vendor heavily involved, consider daily check-ins
 - ▶ Access to CRO tracker of Requests?





Post-Game:

- ▶ Support author of any responses; Meet the deadlines!
- ▶ Author/complete any CAPAs as needed
- ▶ Share knowledge with entire Clin Ops team!

Common Inspection Findings



FDA Inspections Common Findings*

- ▶ Failure to ensure proper monitoring of the study and ensure the study is conducted in accordance with the protocol and/or investigational plan.
 - ▶ e.g. Overuse of eligibility “packets”
- ▶ Failure to maintain and/or retain adequate records in accordance with 21 CFR 312.57;
 - ▶ accountability for the investigational product
 - ▶ investigator statement (Form FDA 1572)
 - ▶ Financial disclosures
- ▶ Failure to submit an Investigational New Drug (IND) application or IND safety report.
- ▶ Inadequate subject protection; informed consent issues.
 - ▶ e.g. complicated ICF versions; country & site level



*BIMO Fiscal Year 2023 Metrics

FDA

FDA Inspections Common Findings*

- ▶ Failure to select qualified investigators and/or monitors, ensure proper monitoring of the study and ensure the study is conducted in accordance with the protocol and/or investigational plan.
- ▶ Failure to notify FDA of termination of investigator.
- ▶ Failure to submit current list of all participating investigators to FDA at six-month intervals after FDA approval of the study.



FDA

*BIMO Fiscal Year 2023 Metrics

EMA Inspection Common Findings

- ▶ GDPR/ Confidentiality & Data Integrity:
 - ▶ Participants' personal data protection
 - ▶ Potential unblinding
 - ▶ e.g. via IP supply process
 - ▶ Secure document sharing with Sponsor
 - ▶ e.g. emailing non-EDC data to Sponsor
- ▶ Study implementation:
 - ▶ Safety reporting – under-reporting of AEs and SAEs
 - ▶ Protocol deviations – prospectively defined, document eligibility waivers granted



EMA Inspection Common Findings

- ▶ Study sites:
 - ▶ Define sponsor's protocol approval date
 - ▶ e.g. Ensuring sites are trained after IRB/EC approvals
 - ▶ Monitoring procedures and frequency
 - ▶ e.g. Inspector compares first IMV timing after patient enrolled to the CMP
 - ▶ Lab sample processing
 - ▶ Protocol and eCRF inconsistency
 - ▶ Open issues not tracked and closed on time
- ▶ TMF deficiencies:
 - ▶ Specify essential documents and timely filing.
 - ▶ Appropriate access
 - ▶ Ongoing review including unblinded reviews



EMA Inspection Common Findings

- ▶ Qualification & Training:
 - ▶ Sponsor approval of monitors not documented
 - ▶ Monitors' training and qualification insufficient
 - ▶ Delegation and training of site staff
- ▶ Study Plans and SOPs:
 - ▶ Lack of SOPs for essential trial processes
 - ▶ Study plans with insufficient detail
 - ▶ Systems validations not performed or documented



References

- ▶ EMA GCP Annual report Nov 2024
- ▶ FDARA section 902 Annual Report on Inspections FY 2023
- ▶ <https://datadashboard.fda.gov/ora/cd/inspections.htm>
- ▶ <https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-clinical-practice/good-clinical-practice-gcp-inspection-procedures>



THANK YOU

