Clinical Research Community Meeting

Post IRB Approval Monitoring and Auditing of Research

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Date: November 19, 2025
Title: Post IRB Approval Monitoring and Auditing of Research –
Is It Just the IRB?—Auditing Requirements (Electronic, In-Person)

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Learning Goals:

1. Differentiate between a not-for-cause, targeted, and for-cause audit
2. Describe the purpose of not for cause audits
3. Describe the components of a remote versus in-person audit
4. Describe the steps to take when notified of an audit



We are not here to take you by surprise!

What is an Audit?

ICH GCP E6(R3)

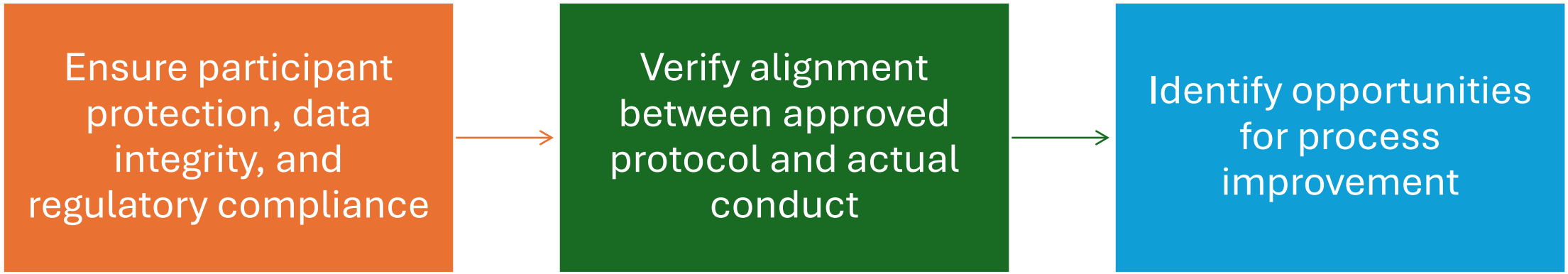
A **systematic** and **independent examination of trial-related activities and records** performed by the sponsor, service provider (including contract research organization (CRO)) or institution to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, applicable standard operating procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

What is Monitoring?

ICH GCP E6(R3)

The act of **overseeing the progress** of a clinical trial, and ensuring that it is conducted, recorded and reported in accordance with the protocol, SOPs, GCP and the applicable regulatory requirement(s).

The Purpose of Post-Approval Audits

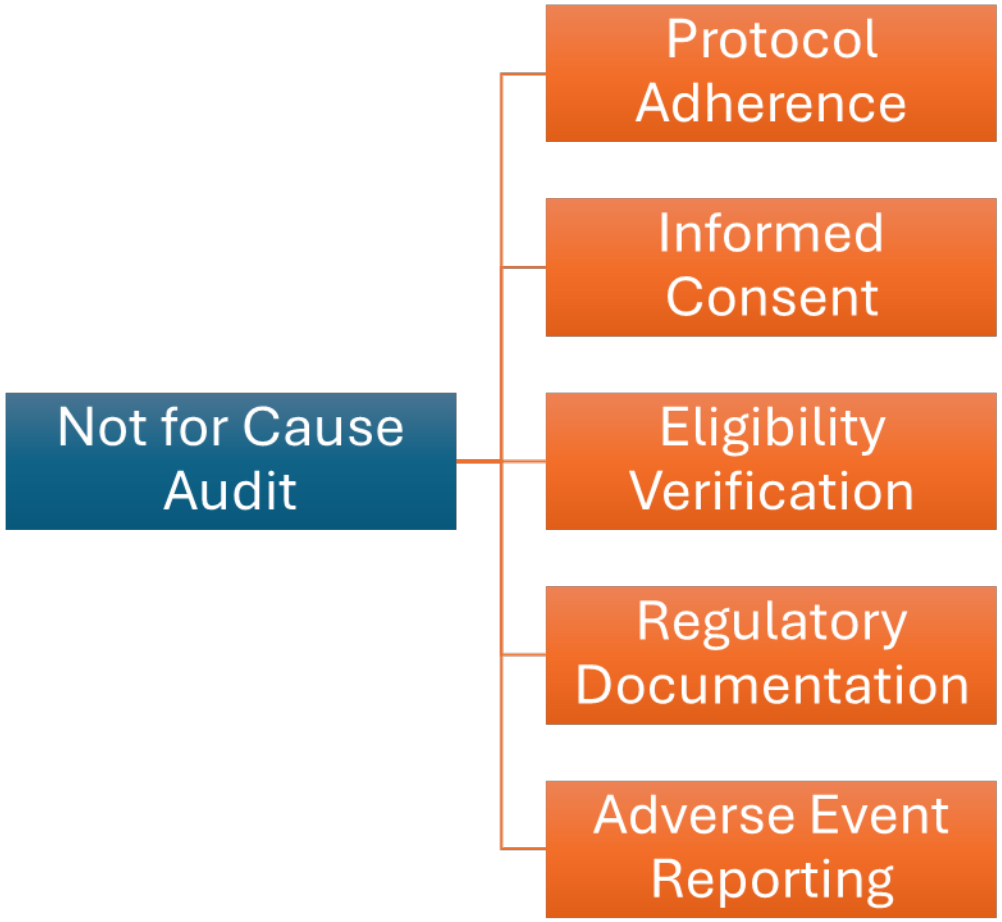


Differentiating Between a “Not for Cause” &“For-Cause Audit”

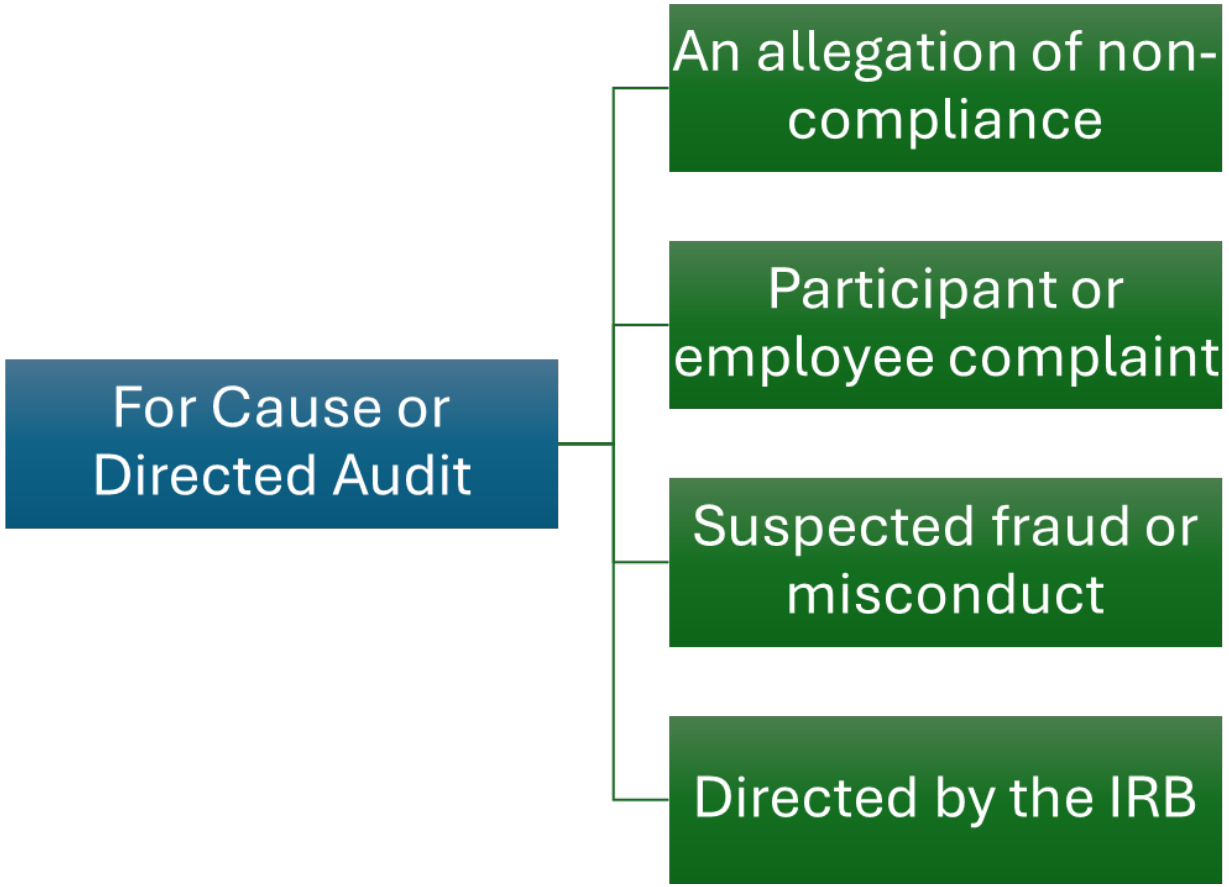
Not for Cause Audit (Routine, Random)

Routine quality assurance review of research to ensure regulatory compliance and promote continuous improvement

- Conducted on a routine or random basis
- Emphasize education and process improvement



For Cause or Directed Audit



ECOG-ACRIN cancer research group

SWOG CANCER RESEARCH NETWORK

Baystate Health

Human Research Protection Program (HRPP)

FDA

Who Conducts Audits?

GOG PARTNERS A GOG Foundation Program

What steps are taken if the FDA or other external agency contacts you?

- Inform the HRPP Director immediately
- HRPP will assist the investigator in preparation for the audit
- Reports from regulatory audits must be submitted to the HRPP, Department Chair and affected ancillary services.

Related Policies

*HRPP SOP's 1.12.3 Audits and Inspections by External Agencies and Others

**BC 10.180 – Audit/Monitor Visit: Preparation, Conduct and Follow-Up.

In Person vs Remote Audits and Monitoring





In Person vs Remote Audits

Key Similarities:

- Focus on GCP and protocol compliance
- Review of essential documents (e.g., ICFs, CRFs, AE logs)
- Verification of data accuracy and subject eligibility
- PI oversight and delegation logs review

In-Person Audit

- Physical access to source documents
- Direct observation of study conduct
- Verification of regulatory binders and drug storage
- Staff interviews and training logs
- Facility tour and equipment inspection

Remote Audit

- Pre-audit document submission via secure portal
- EMR system access or redacted PDF uploads
- Virtual site tour (live or recorded)
- Video interviews with key personnel
- Screen sharing for monitoring logs and systems



I was notified of an audit. What do I do?

Be Prepared!

- ***Audit readiness starts long before*** you get a notification from your internal quality team (EQA) or regulators.
- ***Audit preparedness isn't a one-time event*** – it's a culture of compliance, documentation, and continual improvement.



Steps to Take When Notified of an Audit

- How to Stay Audit Ready
- Understand the Type of Audit
- Pre-Audit Preparation
- During the Audit
- After the Audit

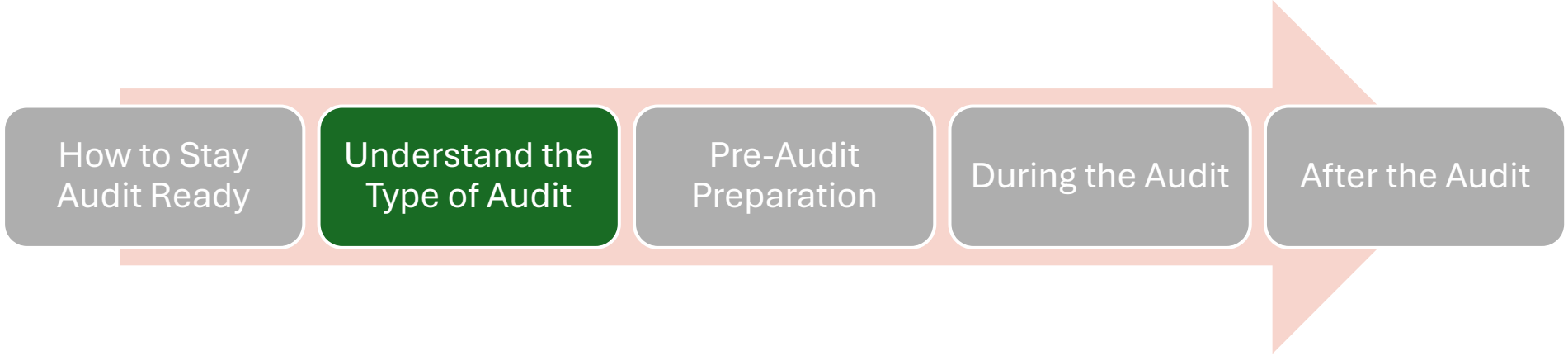


How to Stay Audit Ready | Understand the Type of Audit | Pre-Audit Preparation | During the Audit | After the Audit

Audits shouldn't cause panic – they should confirm readiness!

How to Stay "Audit Ready"

- ✓ Maintain complete and current regulatory documentation in Florence (consents, eligibility logs, training logs, CRFs)
- ✓ Conduct self-checks using EQA as a resource
- ✓ Request targeted audit or spot checks from the EQA – after your first few subjects, mid-study, or at close-out.
  - Think of this as your "wellness visit" - check how health your study conduct is before an external review!
- ✓ Invite EQA to review specific elements (e.g., consent process, RedCap data, Florence Binder)



✓ Who is conducting the audit?

Is it the sponsor, FDA, or another external agency? Is it Baystate IRB/HRPP?

- Investigators must immediately notify the HRPP when they receive an audit or inspection announcement from: federal agencies (HHS/OHRP, FDA), other regulatory bodies, or external sponsors/cooperative groups.
- See *Human Research Protection Program SOPs (revised 02.27.2024), Section 1.12.3*

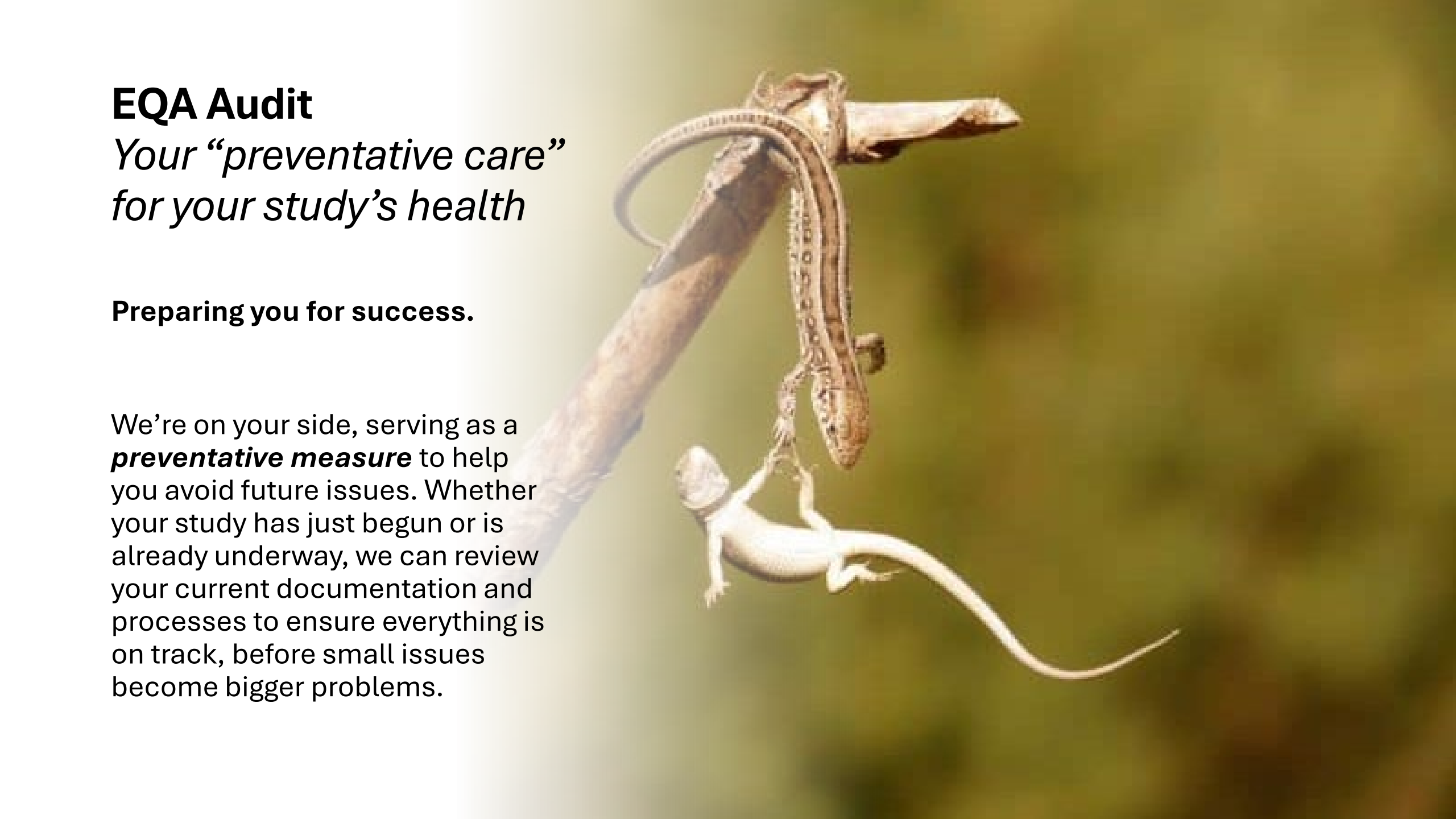
✓ Review the notification letter or email for focus areas and timelines

EQA Audit

Your “preventative care” for your study’s health

Preparing you for success.

We’re on your side, serving as a ***preventative measure*** to help you avoid future issues. Whether your study has just begun or is already underway, we can review your current documentation and processes to ensure everything is on track, before small issues become bigger problems.





Pre-Audit Preparation: Step-by-Step

- ✓ Acknowledge Receipt of the Notification Letter promptly
  - ❑ Confirm the audit date
- ✓ Inform the PI and study team of the audit
- ✓ Ensure remote access readiness
  - ❑ Ensure the auditor has access to Florence e-Binder, OnCore, Redcap
- ✓ Conduct an Internal Review "Health-Check"
  - ❑ Ensure all documentation is current, complete, and signed.
- ✓ Gather Key Study Materials
  - ❑ Regulatory and Essential Documents

How to Stay Audit Ready | Understand the Type of Audit | Pre-Audit Preparation | **During the Audit** | After the Audit



- ✓ Be organized and transparent
- ✓ Be available
- ✓ Provide the requested documents
- ✓ Maintain professional communication and take notes on auditor questions
- ✓ Clarify questions if unsure

How to Stay Audit Ready | Understand the Type of Audit | Pre-Audit Preparation | During the Audit | **After the Audit**



✓ Debrief Immediately
- Review preliminary findings with the team
- Document any verbal feedback

✓ Respond to Findings
- Provide written responses or action plans by the specified deadline
- Implement corrective actions and track follow-up

✓ Share Lessons Learned
- Disseminate key takeaways to your research team or department
- Use audit outcomes for educational opportunities

Key Takeaways

Goal: Audit readiness as a habit in your every day workflow.

- Post-approval audits are about continuous oversight, not punishment
- Early communication with the EQA Team helps teams prepare appropriately
- Proactive compliance and documentation readiness reduce risk and stress



Questions?

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Announcements from The Office of Research

Happy Thanksgiving

