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A Review of Audit Case Studies

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Goal

- Understand the how research compliance helps **facilitate research.**
  - Reputation internally
  - Reputation externally

Why for-cause audits?

- Who needs them?
- Why are they important?

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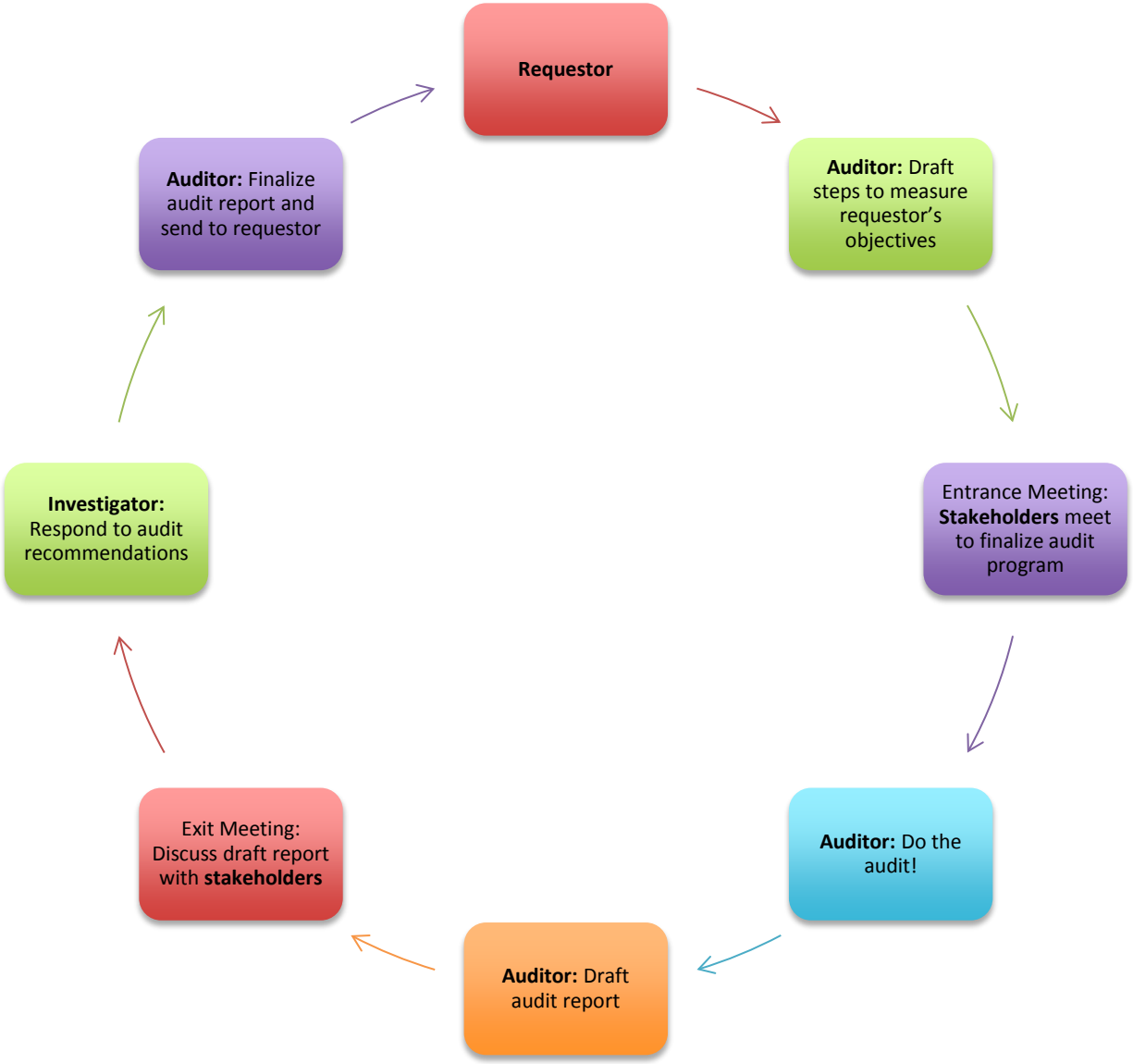
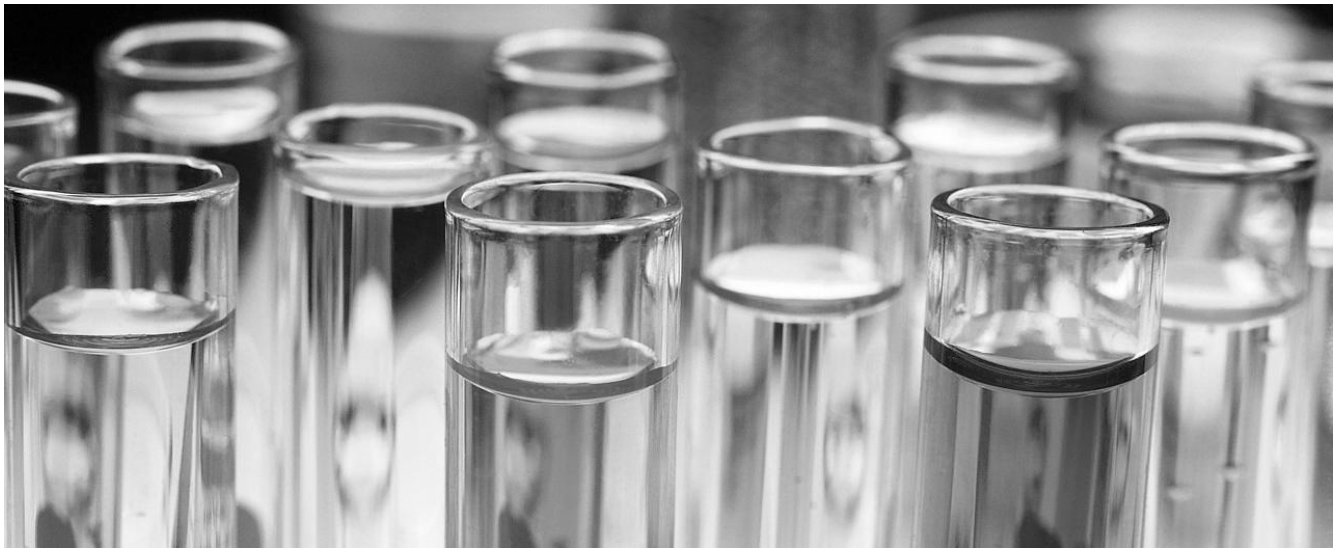
For-cause audit flow



What's SO GREAT ABOUT this?

Transparency



Case study #1

- Oncology: Consent
- AE reports
- Protocol adherence

Case 1

- **Scene:**
  - Out-patient/in-patient clinic with national referrals to the clinician (well-known oncologist)
  - 1000+ new patients referred annually, with 50-70% enrolled in 5+ research protocols
  - Protocols include intervention and 5-year adverse event follow-up

Case 1

- **Audit Prompt:**
  - IRB continually concerned about the lack of adverse event reporting on annual reports
  - Results of internal compliance office cursory review of research consents

Case 1

- **Audit Objectives:**
  - Was legally effective informed consent documented for each participant?
  - Have all adverse events been reported appropriately?
  - Was the protocol followed for each participant?

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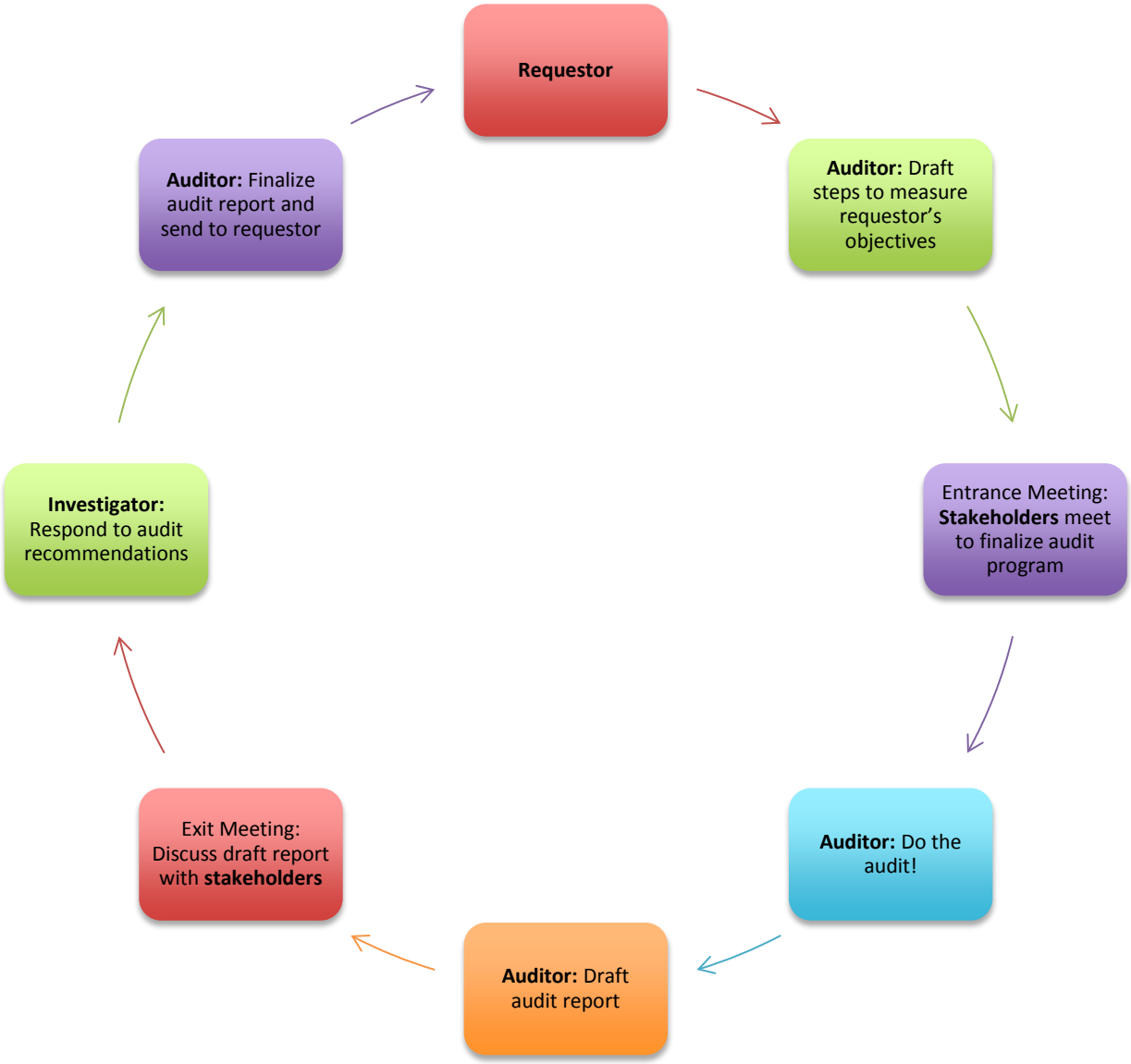

Case 1

- **Audit Findings:**
  - Consent
  - Adverse events
  - Protocol followed
  - Record-keeping processes

Case 1

- **Conclusions:** YOU!
  - Compliance perspectives
  - Ethical perspectives

Case 1

- **Recommendations:** YOU!
  - Consent
  - Adverse events
  - Protocol adherence
  - Record-keeping

Case 1

- **Results:**
  - All studies were terminated
  - All study data were requisitioned by institution (consents, notes, databases, etc.)
  - Investigator required to redact all publications
  - Investigator lost research privileges at the institution for 2 years, with the option to begin again after completing robust training in conducting research with a single research project

Case 1

- **Lessons Learned:**
  - Institution:
    - Heed **hunches** about problems while being **fair and objective**
    - Have **checks and balances** in place to measure if training is effective
  - Research team:
    - Understand your **responsibilities** and know the **consequences** for failure
    - Ensure you have enough **resources** to successfully manage your projects

Case study #2

- Genetics: Consent
- Release of rights

Case 2

- **Scene:**
  - Investigator is an internationally recognized expert in certain rare genetic diseases
  - IRB perspective = difficult investigator
  - Investigator perspective = inexpert IRB

Case 2

- **Audit Prompt:**
  - Research team requested to add existing specimens to an existing repository for rare genetic disorders
  - Patients want to provide specimens for research into the cause of the rare genetic diseases
  - IRB requires copy of research consent and release of specimen/rights to research results from the organization
  - Research team refused to provide these documents, and the IRB denied the request to add specimens to repository
  - Research team reported having obtained specimens in an annual report to the IRB

Case 2

- **Audit Objectives:**
  - Does the research team understand their responsibilities to collect/maintain informed consent for each specimen, and to obtain documentation releasing the specimen/rights to research results?
  - Is a consent form available for each specimen maintained in the repository?
  - For the additional specimens in question, has the research team obtained consent forms and releases of specimens/rights to results?

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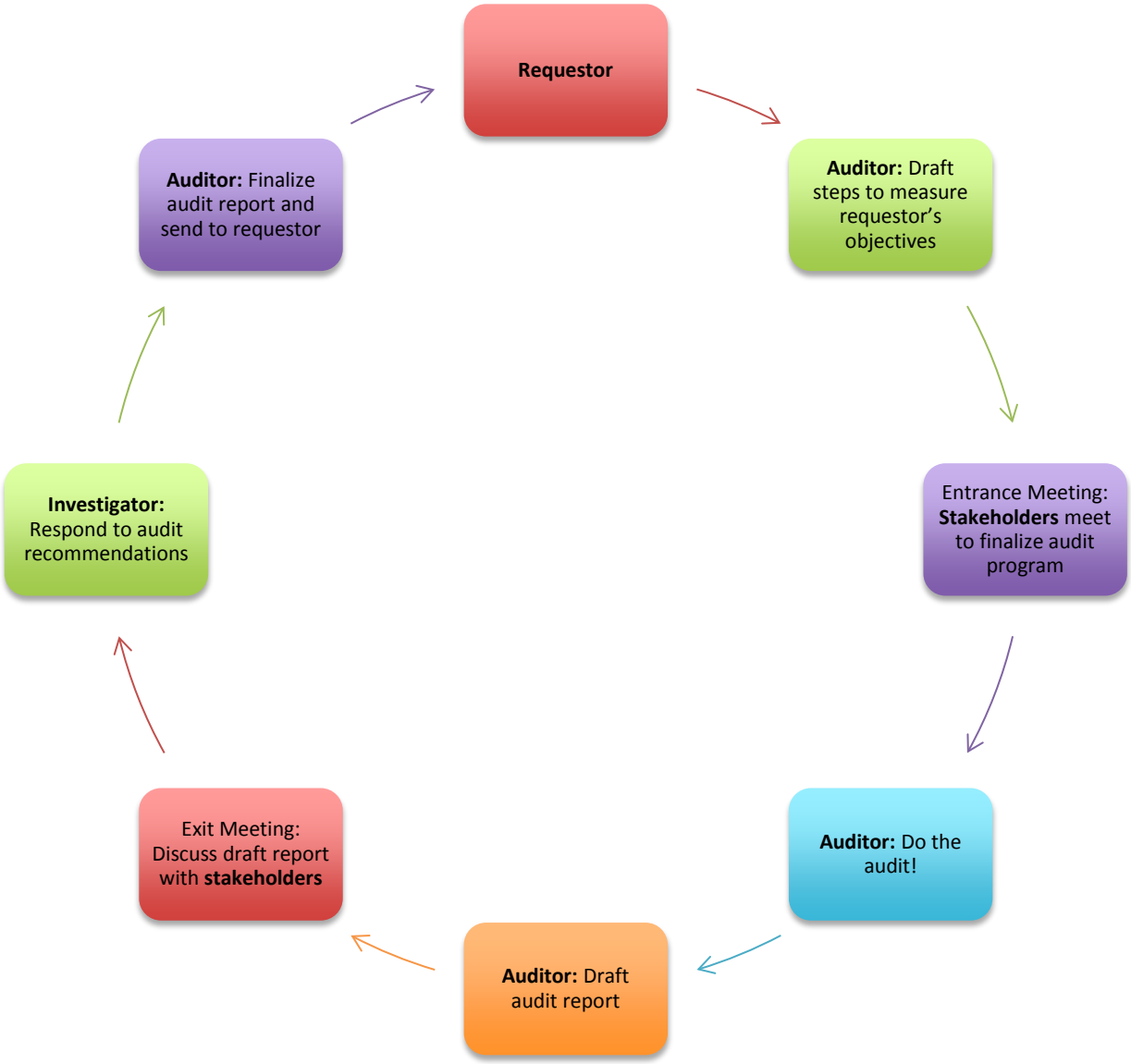

Case 2

- **Audit Findings:**
  - In identical individual interviews, all members of research team answered questions about receipt and storage of specimens and documentation accurately
  - The auditors completed the retrieval process for consents and specimens easily
  - Documents for the new specimens were present

Case 2

- **Conclusions:** YOU!
  - Compliance perspectives
  - Ethical perspectives

Case 2

- **Recommendations:** YOU!

Case 2

- **Results:**
  - Research team demonstrated accurate understanding of the research process
  - Research team asked to create and submit standard operating procedures for receiving specimens/documents and storage of both
  - The IRB approval for the project was reinstated

Case 2

- **Lessons Learned:**
  - Institution and Research Team:
    - Sometimes it **takes time to understand** one another
    - Don't jump to conclusions
      - Find a way to **communicate**
      - Look for a **mediator**

Summary

- Good communication is hard. Transparency will take you far!
- Checks and balances are empowering:
  - Everyone knows their responsibilities.
  - They have the resources they need.
  - They can measure compliance on their own.

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Questions

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